As filed with the Securities and Exchange Commission on January 21, 2025

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

SALARIUS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	46-5087339
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2450 Holcombe Blvd.
Suite X
Houston, TX 77021
713-913-5608
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

David J. Arthur
President and Chief Executive Officer
2450 Holcombe Blvd.
Suite X
Houston, TX 77021
713-913-5608
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Andrew L. Strong, Esq. Stephen M. Nicolai, Esq. Hogan Lovells US LLP 609 Main Street, Suite 4200 Houston, TX 77002 (713) 632-1400	Jeffrey Kuras, Esq. Emily J. Johns, Esq. Honigman LLP 2290 First National Building 600 Woodward Avenue Detroit, MI 48226-3506 (313) 465-7454	Michael Nertney, Esq. Ellenoff Grossman & Schole LLP 1345 Avenue of the Americas New York, NY 10105 (212) 370-1300

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of the registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. Salarius may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION**
DATED JANUARY 21, 2025

Shares of Common Stock
or
Pre-Funded Warrants to Purchase up to Shares of Common Stock
Representative Warrants to Purchase up to Shares of Common Stock
Up to Shares of Common Stock Issuable Upon Exercise of Pre-Funded Warrants and Representative Warrants

Salarius is offering shares of its common stock, par value $0.0001 per share (the "common stock") at a public offering price of $ per share.

Salarius is also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of Salarius' outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants to purchase shares of common stock, in lieu of shares of common stock. The purchase price of each pre-funded warrant will be equal to the public offering price for the common stock in this offering, minus $0.0001. Each pre-funded warrant is exercisable for one (1) share of Salarius' common stock and has an exercise price of $0.0001 per share. For each pre-funded warrant that Salarius sells, the number of shares of common stock Salarius is offering will be reduced on a one-for-one basis. This prospectus also relates to the offering of common stock issuable upon exercise of the pre-funded warrants. Salarius collectively refers to the shares of common stock and pre-funded warrants offered hereby and the shares of common stock underlying the pre-funded warrants as the "securities."

The underwriters have the option to purchase up to additional shares of Salarius' common stock solely to cover over-allotments, if any, at the price to the public, less the underwriting discounts and commissions. The over-allotment option is exercisable for 45 days from the date of this prospectus.

Salarius' common stock is listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "SLRX." On January 17, 2025, the last reported sale price of Salarius' common stock on Nasdaq was $2.69. The recent market price used throughout this prospectus may not be indicative of the final public offering price. The final public offering price will be determined through negotiation between Salarius and the underwriters based upon a number of factors, including Salarius' history and its prospects, the industry in which Salarius operates, Salarius' past and present operating results and the general condition of the securities markets at the time of this offering and may be at a discount to the current market price.

You should also read this prospectus, together with additional information described under the heading "Where You Can Find More Information" carefully before you invest in any of Salarius' securities.

Salarius is a "smaller reporting company" as defined under the federal securities laws and, as such, Salarius has elected to comply with certain reduced public company reporting requirements for this prospectus and future filings. Please see "Prospectus Summary – Implications of Being a Smaller Reporting Company."

Investing in Salarius' securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 25 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

	Per Share[1]	Per Pre-Funded Warrant[1]	Total
Public offering price	$	$	$
Underwriting discounts and commissions[2]	$	$	$
Proceeds to Salarius, before expenses[3]	$	$	$

(1) The public offering price and underwriting discount corresponds to a public offering price per share of common stock of $ ($ net of the underwriting discount) and to a public offering price per pre-funded warrant of $ ($ net of the underwriting discount).
(2) Salarius has agreed to reimburse the representative for certain expenses and issue the representative, or its designees, warrants to purchase up to 10% of the number of shares of common stock and pre-funded warrants sold in this offering, including shares of common stock sold pursuant to the over-allotment option, if any. See "Underwriting" on page 185 for additional information regarding underwriting compensation.
(3) The above summary of offering proceeds does not give effect to any proceeds from the exercise of any warrants being issued in this offering.

Salarius has granted a forty-five (45) day option to the underwriters to purchase additional shares of common stock (up to 15% of the aggregate number of shares of common stock and/or pre-funded warrants sold in this offering) solely to cover over-allotments, if any.

The underwriters expect to deliver the securities to the purchasers in the offering on or about , 2025.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Ladenburg Thalmann

The date of this prospectus is , 2025.

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References to "*Salarius*" and "*Decoy*" in this prospectus refer to Salarius Pharmaceuticals, Inc. and Decoy Therapeutics, Inc., respectively. References to the "*combined company*" refer to Salarius and its wholly owned subsidiary, Decoy, after the Merger, assuming the Merger is consummated. Except as otherwise noted, references to "*we*," "*us*" or "*our*" refer to Salarius. References to "*First Merger Sub*" refer to Decoy Therapeutics MergerSub I, Inc., a newly formed, wholly owned subsidiary of Salarius and references to "*Second Merger Sub*" refer to Decoy Therapeutics MergerSub II, LLC, a newly formed, wholly owned subsidiary of Salarius.

References to the "*Merger Agreement*" refer to that certain Agreement and Plan of Merger dated as of January 10, 2025, among Salarius, First Merger Sub, Second Merger Sub and Decoy, as amended from time to time.

References to the "*Merger*" refers collectively to the merger of First Merger Sub with and into Decoy, with Decoy surviving as the surviving entity and as a wholly owned subsidiary of Salarius, and the merger of Decoy with and into Second Merger Sub, with Second Merger Sub being the surviving entity and continuing under the name "Decoy Therapeutics, LLC" as a wholly owned subsidiary of Salarius, in each case as contemplated under the Merger Agreement.

ABOUT THIS PROSPECTUS

Neither Salarius nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus that Salarius has authorized for use in connection with this offering. Salarius takes no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you.

This prospectus does not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus in any jurisdiction to or from any person to whom or from whom it is unlawful to make such offer or solicitation of an offer in such jurisdiction.

The underwriters are offering to sell, and seeking offers to buy, Salarius' securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus and any free writing prospectus that Salarius has authorized for use in connection with this offering is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus or of any sale of Salarius' securities. Salarius' business, financial condition, results of operations, and prospects may have changed since such dates. It is important for you to read and consider all information contained in this prospectus in making your investment decision. You should read this prospectus before investing in Salarius' securities.

Unless otherwise indicated, information contained in this prospectus concerning Salarius' and Decoy's respective businesses and the industries and markets in which they operate, including with respect to their business prospects, market position and opportunity, and the competitive landscape, is based on information from Salarius' and Decoy's respective management's estimates, as well as from industry publications, surveys, and studies conducted by third parties. Salarius' and Decoy's respective management's estimates are derived from publicly available information, their knowledge of the respective party's business and industry, and assumptions based on such information and knowledge, which they believe to be reasonable. In addition, while Salarius and Decoy believe that information contained in the industry publications, surveys, and studies has been obtained from reliable sources, neither party has independently verified any of the data contained in these third-party sources, and the accuracy and completeness of the information contained in these sources is not guaranteed.

Although Salarius is not aware of any misstatements regarding the market and industry data presented in this prospectus, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" in this prospectus and any related free writing prospectus. Accordingly, you should not place undue reliance on this information.

For investors outside the United States: Salarius and the underwriters have not done anything that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for those purposes is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside of the United States.

Basis of Presentation

On June 14, 2024, Salarius filed a Certificate of Amendment to its amended and restated certificate of incorporation (the "Certificate of Amendment") with the Secretary of State of the State of Delaware to effect a 1-for-8 reverse stock split of Salarius' issued and outstanding shares of common stock, par value $0.0001 per share (the "reverse split"), which became effective on that date. All historical share and per share amounts with respect to Salarius reflected throughout this prospectus have been adjusted to reflect the reverse split.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus may constitute "forward-looking statements" within the meaning of the U.S. federal securities laws, including the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding the plans, strategies and prospects, both business and financial, of Salarius, Decoy and the combined company. These statements are based on the beliefs and assumptions of Salarius' and Decoy's management. Although Salarius and Decoy believe that these plans, intentions and expectations reflected in or suggested by these forward-looking statements are reasonable, the parties cannot assure you that they will achieve or realize these plans, intentions or expectations. Forward-looking statements are inherently subject to risks, uncertainties and assumptions. Generally, statements that are not historical facts, including statements concerning possible or assumed future actions, business strategies, events, or results of operations, are forward-looking statements. These statements may be preceded by, followed by or include the words "believes," "estimates," "expects," "projects," "target," "goal," "forecasts," "may," "will," "potential," "should," "would," "could," "future," "seeks," "plans," "predicts," "propose," "scheduled," "anticipates," "intends," or similar expressions.

Forward-looking statements in this prospectus include, but are not limited to, statements about the following:

- the expected benefits of, and potential value created by, the Merger for the securityholders of Salarius and Decoy;
- the likelihood of the satisfaction of certain conditions to the completion of the Merger, including the conditions related to this offering, whether and when the Merger will be consummated and that Salarius' common stock remains listed on Nasdaq;
- the expected amount of Salarius' cash amount to be delivered at the closing of the Merger and Salarius' ability to control and correctly estimate its operating expenses and its expenses associated with the Merger, including potential litigation expenses;
- the effects of the Merger and this offering on the ownership percentages of the Decoy's stockholders and Salarius' stockholders in the combined company;
- the plans, strategies and objectives of management for future operations, including the execution of integration plans and the anticipated timing of filings, commencement of preclinical studies or clinical trials and release of data from such studies or trials;
- plans to develop and commercialize additional products candidates including planned preclinical, clinical, regulatory, commercialization and manufacturing activities;
- the attraction and retention of highly qualified personnel;
- the ability to protect and enhance the combined company's products and intellectual property;
- developments and projections relating to the combined company's competitors or industry;
- the combined company's financial performance;
- Salarius' or Decoy's relationships and actions with third parties;
- Salarius' and the combined company's ability to maintain the listing of its shares of common stock on Nasdaq, and the potential liquidity and trading of such shares of common stock;
- the ability of Salarius and the combined company to successfully manage its cash and cash equivalents and any anticipated proceeds from this offering or other financing transactions;
- Salarius' and the combined company's ability to acquire sufficient sources of funding if and when needed;
- future regulatory, judicial and legislative changes in Salarius' or Decoy's respective industries; and

- the use of proceeds from this offering.

These forward-looking statements should not be relied upon as predictions of future events as Salarius and Decoy cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including "believes," "expects," "may," "will," "should," "seeks," "intends," "plans," "pro forma," "estimates," or "anticipates" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation:

- Salarius' and Decoy's stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and this offering;
- the Merger consideration may have greater or lesser value at the closing of the Merger than at the time the Merger Agreement was signed;
- failure to complete the Merger may result in either party paying a termination fee or expenses to the other party and could harm the future business and operations of each company;
- if the conditions to the Merger are not met, including failure to consummate this offering, or failure to comply with the continued listing standards of Nasdaq, the Merger may not occur;
- the timing of the consummation of the Merger is uncertain as is the ability of each of Salarius and Decoy to consummate the Merger;
- the Merger may be completed even though material adverse changes may occur;
- Salarius may not be able to correctly estimate its operating expenses and its expenses associated with the Merger and may have a significantly lower cash on the closing date of the Merger than currently estimated;
- Salarius may not be able to maintain its Nasdaq listing following the Merger Closing;
- as a result of any adjustments in the exchange ratio set forth in the Merger Agreement and this financing, Salarius' stockholders or Decoy's stockholders may own less of the combined company than is currently anticipated;
- the market price of Salarius' common stock may decline following the Merger;
- restrictions in the Merger Agreement may prevent Salarius and Decoy from entering into a business combination with another party at a favorable price;
- certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement;
- the combined company may never earn a profit;
- the combined company will be subject to the uncertainties associated with the clinical development and regulatory approval of its product candidates including potential delays in the commencement, enrollment and completion of clinical trials and that the results of prior clinical trials may not be predictive of future results;
- the combined company will be required to raise additional funds to finance its operations and remain a going concern and may be required to do so sooner than it expects;
- the combined company may not be able to raise additional funds when necessary, and/or on acceptable terms;

- the combined company's small public float, low market capitalization, limited operating history, and lack of revenue may make it difficult and expensive for the combined company to raise additional funds;
- Salarius and Decoy may not be able to protect their respective intellectual property rights;
- there may be changes in expected or existing competition for the combined company's product candidates;
- the Merger will result in changes to the combined company's board of directors that may affect the combined company's business strategy and operations;
- both companies expect the price of the combined company's common stock may be volatile and may fluctuate substantially following the Merger and the transactions contemplated thereby;
- if the combined company were to be delisted from Nasdaq, it could reduce the visibility, liquidity and price of its common stock;
- a significant portion of the combined company's total outstanding shares of common stock may be sold into the public market at any point, which could cause the market price of the combined company's common stock to drop significantly, even if the combined company is doing well;
- there may be adverse reactions or changes in business relationships resulting from announcement or completion of the Merger;
- the combined company will have broad discretion in the use of its cash reserves and may not use them effectively;
- the combined company expects to continue to incur increased costs as a result of operating as a public company, and its management will be required to devote substantial time to compliance initiatives and corporate governance practices;
- the combined company does not anticipate paying any cash dividends on its capital stock in the foreseeable future;
- provisions in the combined company's certificate of incorporation, its bylaws or Delaware law might discourage, delay or prevent a change in control of the company or changes in its management, which may depress the price of its common stock;
- securities analysts' published reports could cause a decline in the price of the combined company's stock.

The foregoing risks should not be construed as exhaustive and should be read in conjunction with statements that are included herein. For further discussion of the factors that may cause Salarius, Decoy or the combined company's actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, or for a discussion of risks associated with the ability of Salarius and Decoy to complete the Merger and the effect of the Merger on the business of Salarius, Decoy and the combined company, see the section entitled "*Risk Factors*" in this prospectus.

If any of these risks or uncertainties materialize or any of these assumptions prove incorrect, the results of operations of Salarius, Decoy or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this prospectus are current only as of the date of this prospectus. Salarius and Decoy do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any statement is made, the occurrence of unanticipated events or any new information that becomes available in the future.

Salarius discusses in greater detail many of these risks, uncertainties and assumptions under the heading "*Risk Factors*." Any forward-looking statement made by Salarius in this prospectus speaks only as of the date on which it was made. Salarius expressly disclaims any obligation or undertaking to release publicly any updates or revisions to

any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions, or circumstances on which any such statement is based.

You should read this prospectus and with the understanding that Salarius', Decoy's and the combined company's actual future results, levels of activity, and performance as well as other events and circumstances may be materially different from what Salarius, Decoy and the combined company expects. Salarius qualifies all of the forward-looking statements in this prospectus by these cautionary statements.

PROSPECTUS SUMMARY

This summary highlights certain information about Salarius, Decoy, this offering, the Merger and information appearing elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before making an investment decision. To fully understand this offering and its consequences to you, you should read this entire prospectus carefully, including the factors described under the heading "Risk Factors" in this prospectus beginning on page 25, together with any free writing prospectus Salarius has authorized for use in connection with this offering and the financial statements and all other information included in this prospectus.

Overview of Salarius Pharmaceuticals, Inc.

Salarius is a clinical-stage biopharmaceutical company that has been focused on developing effective treatments for patients with cancer with high, unmet medical need. Specifically, Salarius has been concentrated on developing treatments for cancers caused by dysregulated gene expression (i.e., genes which are incorrectly turned on or off). Salarius has two classes of drugs that address gene dysregulation: targeted protein inhibitors and targeted protein degraders. Salarius' technologies have the potential to work in both liquid and solid tumors. Salarius' current pipeline consists of two small molecule drugs: (1) SP-3164, a targeted protein degrader, and (2) seclidemstat ("SP-2577"), a targeted protein inhibitor.

SP-3164 – Targeted Protein Degradation

Salarius' plan had been to develop SP-3164 in high unmet need hematological indications and solid tumors. Salarius' goal was to file an investigational new drug ("IND") application with the U.S. Food and Drug Administration ("FDA") for SP-3164 in the first half of 2023, and begin a Phase 1/2 clinical trial in the second half of 2023, however the lack of funding required Salarius to curtail spending necessary to begin the clinical trial program. The combined company plans to integrate Salarius' assets, particularly the proprietary compound SP-3164, to expand its opportunities in creating a novel class of peptide conjugates called peptide-based proteolysis targeting chimeras (PPROTACs).

SP-2577 Ewing Sarcoma

On July 19, 2024, Salarius announced that it determined to close its ongoing Phase 1/2 clinical trial evaluating SP-2577 for Ewing sarcoma, including closing the remaining clinical trial sites. Salarius terminated the ongoing clinical trial in an effort to conserve cash. Salarius continues supporting The University of Texas MD Anderson Cancer Center ("MDACC") in MDACC's sponsored clinical trial evaluating SP-2577 in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia. The trial remains on partial clinical hold following a serious and unexpected grade 4 adverse event while MDACC works with the FDA to resolve the partial clinical hold.

Recent Developments

Entry into Merger Agreement with Decoy Therapeutics, Inc. ("Decoy")

On August 8, 2023, Salarius announced that it retained Canaccord Genuity, LLC to lead a comprehensive review of strategic alternatives focusing on maximizing stockholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing, or other strategic transactions involving the company. On January 10, 2025, Salarius entered into an Agreement and Plan of Merger (the "Merger Agreement") with Decoy Therapeutics MergerSub I, Inc., a Delaware corporation and a wholly owned subsidiary of Salarius ("First Merger Sub"), Decoy Therapeutics MergerSub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Salarius ("Second Merger Sub"), and Decoy. Pursuant to the Merger Agreement, Salarius will combine with Decoy (the "Merger") by causing First Merger Sub to be merged with and into Decoy, with Decoy surviving the merger as a wholly owned subsidiary of Salarius (the "First Merger"). Immediately following the First Merger, Decoy will merge with and into Second Merger Sub, with Second Merger Sub being the surviving entity and continuing under the name "Decoy Therapeutics, LLC" as a wholly owned subsidiary of Salarius.

Description of Decoy's Business and the Combined Company's Proposed Business

Decoy is a pre-clinical stage biotechnology company that was incorporated on April 17, 2020.

Decoy's proprietary Immediate Peptide/PPMO/P-PROTAC Alpha-helical Conjugate Technology platform ("IMP^{3}ACT™") represents a paradigm shift in peptide conjugate drug discovery and manufacturing, leveraging machine learning ("ML") and artificial intelligence ("AI") tools alongside high- speed synthesis techniques to rapidly engineer, optimize and manufacture peptide conjugates that target serious unmet medical needs. Peptide conjugates are emerging as a major therapeutic drug modality, with the potential to transform multiple therapeutic areas. This innovative class of drugs, exemplified by successful diabetes and weight loss treatments like Ozempic, Wegovy, Mounjaro and ZepBound, combines small a-helical peptides with functional moieties to enhance solubility and extend the duration of action. By decreasing the complexity of peptide conjugate development, Decoy aims to establish itself as a leader in this advancing drug class. Decoy's goal is to build a robust portfolio of novel peptide conjugate therapeutics, initially focusing on infectious diseases and oncology. Through this approach, Decoy intends to revolutionize the design, development, and commercialization of peptide conjugate therapeutics, becoming a fully integrated biopharmaceutical company at the forefront of this exciting field.

The peptide conjugate drug class is extremely modular and flexible, making it applicable to a wide range of human disease states and medical indications. Decoy expects that its drug candidates may be used both chronically, like current diabetes or weight loss drugs, or acutely, as is typical of antiviral treatments. Decoy is planning to engineer its peptide conjugates to be delivered via a variety of routes that can be optimally matched to the targeted disease state, including intranasal and pulmonary inhalation, extended-release dermal patches, oral, subcutaneous (SC) injection, and intravenous. Peptide drug conjugates can also be designed to deliver payloads, including radionucleotides or approved small molecule or biological drugs, to a specific target or tissue of interest, such as cancerous tumors, to achieve highly precise delivery with increased tissue penetration and lower cost compared to antibody-drug conjugates ("ADCs"). As with ADCs, the goal of this strategy is to widen the "therapeutic window" by increasing efficacy while reducing the overall dose and consequent side-effects of the payload. Decoy believes the peptide conjugate modality is ideally suited to this strategy. Decoy believes its integration with Salarius expands the combined company's opportunities to create an additional novel class of peptide conjugates, specifically, peptide-based proteolysis targeting chimeras ("P-PROTACs"), utilizing the Salarius compound SP-3164 as an important building block in these peptide conjugate drugs.

The combined company plans to integrate Salarius' assets, particularly the proprietary compound SP-3164, to expand its opportunities in creating a novel class of peptide conjugates called peptide-based proteolysis targeting chimeras (PPROTACs). SP-3164, which specifically binds to the E3 ligase complex CRLCBRN, is expected to be combined with Decoy's peptide engineering platform to target various disease-relevant intracellular proteins. This integration allows Decoy to leverage the advantages of peptides in protein targeting, potentially expanding the range of targetable proteins beyond what can be achieved with small molecule inhibitors and improving the safety window via peptide based precision medicine tissue targeting.

The combined company's business is expected to focus on developing innovative peptide conjugates as a major therapeutic drug modality. Decoy's proprietary IMP^{3}ACT platform leverages machine learning and artificial intelligence tools alongside high-speed synthesis techniques to rapidly engineer, optimize, and manufacture peptide conjugates targeting significant unmet medical needs. Decoy aims to build a robust portfolio of novel peptide conjugate therapeutics, initially focusing on infectious diseases and oncology, with the goal of becoming a fully integrated biopharmaceutical company at the forefront of this exciting field.

Salarius and Decoy believe the synergies between Decoy and Salarius are evident in their combined approach to drug development. Decoy's expertise in peptide conjugates complements Salarius' small molecule assets. This combination could enable the combined company to address a wider range of diseases and potentially "undruggable" targets. Additionally, the Merger is expected to expand Decoy's focus to include exploratory research on P-PROTACs for metastatic colorectal cancer, while also continuing support for MDACC's ongoing investigator initiated clinical trial evaluating seclidemstat (SP-2577) in combination with azacytidine for certain blood disorders while conducting a thorough review of this small molecule program.

Description of the Merger with Decoy

The Merger is structured as a stock-for-stock transaction pursuant to which all of Decoy's outstanding equity interests will be exchanged based on an exchange ratio for consideration of a combination of (a) shares of Salarius' common stock par value $0.0001 (the "Common Stock") in an amount up to (i) 19.9% of Salarius' total shares outstanding as of January 10, 2025 minus (ii) any shares of Salarius Common Stock issued in any private placement between January 10, 2025 and the effective time of the First Merger (the "First Effective Time"), and (b) shares of Series A Preferred Stock, which is a newly designated series of preferred stock ("Preferred Stock") that is intended to have economic rights equivalent to the Common Stock, but with only limited voting rights, in addition to the assumption of outstanding and unexercised stock options to purchase shares of Common Stock from the Decoy Therapeutics Inc. 2020 Equity Incentive Plan. The number of shares of Common Stock to be issued at Merger Closing (as defined below) and the number of shares of Common stock underlying the Series A Preferred Stock to be issued at closing of the Merger (the "Merger Closing") is based on an exchange ratio which assumes a base value of $28.0 million for Decoy and $4.6 million for Salarius, subject in each case to adjustment based on the balance sheet cash available to each Salarius and Decoy at Merger Closing (excluding any proceeds raised the "Qualified Financing," as defined below). Based on these relative values, before taking into account the dilutive effects of the Qualified Financing, Salarius' legacy stockholders would retain approximately 14.1% of Salarius on an as-converted-to-common basis and, after giving effect to the exchange ratio and the conversion of the Series A Preferred Stock, Decoy stockholders would own approximately 85.9% of Salarius.

The rights of the Series A Preferred Stock will be set forth in a Certificate of Designation of Preferences, Rights and Limitations that Salarius will file with the Secretary of State of the State of Delaware (the "Certificate of Designation"). The Certificate of Designation provides that the preferred stock will be convertible into shares of Common Stock on a 1-for-1000 basis, subject to stockholder approval. Please see "*Description of Capital Stock-Description of Series A Preferred Stock*" for a complete description of the Certificate of Designation and the rights of the Series A Preferred Stock. The Merger was approved by Salarius' board of directors and the board of directors of Decoy. In addition, following the consummation of the Merger, Salarius has agreed to call a special stockholder meeting to approve (i) the conversion of the preferred stock to be issued at Merger Closing into shares of Common Stock (the "Conversion Proposal"), (ii) a new equity incentive plan in form reasonably agreed to by the parties (the "Equity Plan Proposal"), and (iii) if necessary and advisable, a reverse stock split in a ratio to be approved by Salarius' board of directors (the "Reverse Stock Split Proposal" and together with the Conversion Proposal and the Equity Plan Proposal, the "Company Stockholder Matters").

The Merger Agreement contains customary representations and warranties by each of Salarius and Decoy, as well as covenants relating to operating each respective business in the ordinary course prior to Merger Closing. The Merger Closing is conditioned upon, among other things, minimum proceeds from future offerings of at least $6.0 million (collectively, the "Qualified Financing") and the continued listing of Salarius Common Stock on Nasdaq. This financing is intended to satisfy the requirement of a Qualified Financing.

In connection with the execution of the Merger Agreement, Salarius entered into stockholder support agreements (the "Salarius Support Agreements") with certain of its officers and directors, who collectively own an aggregate of approximately 1.38% of the outstanding shares of the Common Stock. The Salarius Support Agreements provide that, among other things, each of the parties thereto has agreed to vote or cause to be voted all of the shares of Common Stock owned by such stockholder in favor of the Company Stockholder Matters at a special or annual meeting of Salarius' stockholders to be held in connection therewith. In addition, Decoy officers and directors, in their capacities as stockholders of Decoy, entered into stockholder support agreements (the "Decoy Support Agreements") with Decoy. The Decoy Support Agreements provide that, among other things, each of the parties thereto has agreed to vote or cause to be voted all of the shares of Common Stock owned by such stockholder in favor of the proposed Merger.

Concurrently and in connection with the execution of the Merger Agreement, certain Decoy officers and directors, and certain of Salarius' directors and officers entered into lock-up agreements with Salarius and Decoy, pursuant to which each such stockholder will be subject to a 180-day lockup on the sale or transfer of shares of Common Stock held by each such stockholder at the Merger Closing, including those shares received by Decoy stockholders in the Merger.

Reasons for the Merger

In approving the Merger, the Salarius board of directors considered the pros and cons of the Merger versus other alternatives, which is likely a liquidation and discontinuation of Salarius if the Merger is not completed, and the opportunities and risks presented with the Merger.

In particular, the Salarius board of directors took into account the following reasons, facts and circumstances in approving the Merger:

- the potential for Decoy's product candidates to create long term value creation for Salarius' stockholders;
- the potential synergies available when combining Salarius' existing technology with Decoy's technology;
- the ability of the business combination to facilitate entry into the growing market for peptide conjugate technology;
- Decoy's commitment to continuing to pursue development of existing Salarius technology;
- the ability to leverage Decoy's experienced management team and established life science investors;
- the potential enhanced ability to raise capital utilizing a broader potential product portfolio;
- Salarius' projected cash position and the difficulties Salarius has encountered in raising sufficient capital on a stand-alone basis;
- the risks of continuing to operate Salarius on a stand-alone basis, including uncertainty regarding Salarius' product development and the need to raise significant additional financing for future clinical and commercial development;
- the low valuation of Salarius on a stand-alone basis currently evidenced by the trading value of Salarius' Common Stock;
- the strategic alternatives to the Merger, including the discussions that the Salarius' management and advisors previously conducted with other potential partners, and the lack of any viable alternatives; and
- the view of Salarius' financial advisor that the consideration is fair, from a financial point of view, to the holders of Salarius' Common Stock.

The Salarius board of directors believed that, as a result of arm's length negotiations with Decoy, Salarius and its management team negotiated the most favorable implied value and equity split for its stockholders that Decoy was willing to agree to, and that the terms of the Merger Agreement include the most favorable terms to Salarius in the aggregate to which Decoy was willing to agree. Immediately prior to signing the Merger Agreement, Salarius' stock price was approximately $1.565 per share, as quoted on Nasdaq on January 10, 2025. Salarius and Decoy agreed that Salarius would have a valuation of $4.6 million, assuming $0 of net cash delivered at Merger Closing, and Decoy would have a valuation of $28.0 million in the Merger at the time of Merger Closing and the parties entered into a non-binding term sheet on October 11, 2024, which included binding exclusivity terms to negotiate the Merger to each party.

The Salarius board of directors also believed, after a thorough review of strategic alternatives and discussions with Salarius' senior management, its financial advisors and legal counsel, that the Merger is more favorable to its stockholders than the potential value that might have resulted from other strategic options available to Salarius, which would likely be a liquidation of Salarius and the distribution of any available cash if the Merger is not consummated.

After giving consideration to these and other factors, the Salarius board of directors approved the Merger, which the Salarius board of directors believes better positions Salarius for long-term success.

Warrant Cancellation Agreement

On January 10, 2025, Salarius entered into a Warrant Cancellation Agreement (the "Warrant Cancellation Agreement") with an accredited investor ("Investor"). Salarius previously issued to the Investor a Series A-1 Common Stock Purchase Warrant to purchase 454,546 shares (on a post-reverse stock split basis) of its common stock pursuant to the offering described in Salarius' Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on May 16, 2023 (the "Warrant"). Pursuant to the Warrant Cancellation Agreement, on January 10, 2025, Salarius paid the Investor an aggregate amount in cash of $350,000 in exchange for the surrender and cancellation of the Warrant.

Securities ELOC Agreement

On December 12, 2024, Salarius entered into a securities purchase agreement (the "ELOC Agreement") with C/M Capital Master Fund, LP (the "Purchaser"), pursuant to which Salarius, subject to the restrictions and satisfaction of the conditions in the ELOC Agreement, has the right, but not the obligation, to sell to the Purchaser, and the Purchaser is obligated to purchase, up to the lesser of (i) $10 million of newly issued shares (the "Purchase Shares") of Salarius' common stock and (ii) the Exchange Cap (as defined below). As consideration for the Purchaser's execution and delivery of the ELOC Agreement, Salarius has agreed to issue to the Purchaser, simultaneously with the delivery of any and all Purchase Shares purchased under the ELOC Agreement, a number of shares of Salarius common stock equal to one percent (1%) of the number of Purchase Shares actually sold in each sale under the ELOC Agreement (the "Commitment Shares" and, together with the Purchase Shares, the "Securities").

On January 13, 2025, Salarius issued and sold 141,000 shares (the "Purchase Shares") of its common stock to the Purchaser pursuant to the "ELOC Agreement. This issuance and sale was made following written notice delivered by Salarius to Investor, directing Investor to purchase the Purchase Shares. Pursuant to the ELOC Agreement, the purchase price paid by the Purchaser was $3.50 per Purchase Share, for an aggregate purchase price of $493,500. Salarius also issued 1,410 shares of its common stock to the Purchaser as commitment shares pursuant to the terms of the ELOC Agreement.

Management Following the Merger

The following table lists names, ages and positions of the individuals who are expected to serve as executive officers and directors of the combined company following completion of the Merger. In addition to Mr. Pierce and Ms. Hibner, following stockholder approval of conversion of the Preferred Stock to be issued upon completion of the Merger, additional non-employee directors will be designated by Decoy and/or Salarius as contemplated by the Merger Agreement.

Name	Age	Position
Executive Officers		
Frederick E. Pierce	63	Chief Executive Officer and Director
Mark J. Rosenblum	71	Chief Financial Officer
Peter Marschel	50	Chief Business Officer
Barbara Hibner	63	Chief Scientific Officer and Director

Summary Risk Factors

Investing in Salarius' securities involves risks. If any of these risks actually occur, Salarius' and the combined company's business, financial condition and results of operations would likely be materially adversely affected. You should carefully consider all the information contained in this prospectus before making a decision to invest in Salarius' securities. In particular, you should consider the risk factors described under "*Risk Factors*" beginning on page 25. Some of these risks related to Salarius', Decoy's and the combined company's business, operations, financial performance and industry, as well as this offering and Salarius' securities, are summarized below.

- The Merger may be completed even though certain events occur prior to the Merger Closing that materially and adversely affect Salarius or Decoy.

- The Exchange Ratio set forth in the Merger Agreement is adjustable based on the Parent Cash Amount and the Company Cash Amount, each of which will be impacted by, among other things, unexpected expenses that could be experienced by Salarius or Decoy during the pre-closing period, which could result in Salarius stockholders owning significantly less of the combined company than currently estimated.
- Stockholders of the combined company may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and the Qualified Financing.
- The historical unaudited pro forma condensed combined financial information may not be representative of the combined company's results after the Merger.
- During the pendency of the Merger, Salarius and Decoy may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.
- Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.
- Pursuant to the terms of the Merger Agreement, Salarius is required to recommend that its stockholders approve the conversion of all outstanding shares of its Series A Preferred Stock into shares of its Common Stock. Salarius cannot guarantee that its stockholders will approve this matter, and if they fail to do so its operations may be materially harmed.
- Because the lack of a public market for Decoy's capital stock makes it difficult to evaluate the value of Decoy's capital stock, the stockholders of Decoy may receive shares of Salarius common stock in the Merger that have a value that is greater than, the fair market value of Decoy's capital stock.
- The combined company may become involved in securities class action litigation that could divert management's attention and harm the combined company's business and insurance coverage may not be sufficient to cover all costs and damages.
- The Merger Agreement between Salarius and Decoy may be terminated in accordance with its terms and the Merger may not be completed.
- Salarius may not be able to effect the Merger pursuant to the Merger Agreement, and failure to complete the Merger could negatively impact Salarius' stock price and the future business and financial results of the Salarius.
- The market price of Salarius' common stock following the Merger may decline as a result of the Merger.
- Salarius and Decoy securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the Merger Closing as compared to their current ownership and voting interest in the respective companies.
- The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or impact its proprietary rights.
- You will experience immediate and substantial dilution if you purchase Salarius' securities in this offering.
- Substantial future sales or other issuances of Salarius common stock could depress the market for Salarius' common stock.
- Salarius has broad discretion in how it uses the proceeds of this offering and may not use these proceeds effectively, which could affect Salarius' results of operations and cause its common stock to decline.

- Salarius does not currently intend to pay dividends on its common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of Salarius common stock.
- The trading price of the shares of Salarius' common stock could be highly volatile, and purchasers of Salarius' common stock could incur substantial losses.
- There is no public market for the pre-funded warrants being offered in this offering.
- Holders of the pre-funded warrants will have no rights as common stockholders until such holders exercise their pre-funded warrants and acquire Salarius common stock.
- Salarius may not receive any additional funds upon the exercise of the pre-funded warrants.
- Significant holders or beneficial holders of Salarius common stock may not be permitted to exercise pre-funded warrants that they hold.
- If the Merger is not completed, Salarius may not be able to otherwise source adequate liquidity to fund its operations, meet its obligations, and continue as a going concern. Salarius' board of directors may decide to pursue a dissolution and liquidation of Salarius. In such an event, there can be no assurances as to the amount or timing of available cash left, if any, to distribute to its stockholders after paying its debts and other obligations and setting aside funds for reserves.
- Salarius' common stock may be subject to delisting from Nasdaq.
- The pendency of the Merger could have an adverse effect on the trading price of Salarius' common stock and its business, financial condition and prospects.
- Decoy's financial condition raises substantial doubt regarding its ability to continue as a going concern.
- Decoy has never generated revenue from product sales and all of Decoy's product candidates are currently in the preclinical stage, and Decoy may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.
- Because Decoy has yet to generate revenue from product sales on which to evaluate its potential for future success and to determine if Decoy will be able to execute its business plan, it is difficult to evaluate Decoys' prospects and the likelihood of success or failure of its business.
- Because early-stage drug development requires major capital investment, as Decoy continues to incur operating losses, it will need to raise additional capital or form strategic partnerships to support its research and development activities in the future.
- If any strategic alliances on which Decoy depends are unsuccessful or are terminated, Decoy may be unable to develop or commercialize certain product candidates and it may be unable to generate revenues from its development programs.
- Since Decoy expects to rely on third parties to conduct, supervise and monitor any future clinical trials, if those third parties fail to perform in a satisfactory manner and one that meets applicable regulatory, scientific and safety requirements, it may materially harm Decoy's business.
- Because the approach Decoy is taking to discover and develop drugs is novel, it may never lead to marketable products.
- If Decoy does not succeed in its efforts to identify or discover additional potential product candidates, your investment may be lost.

These risks and other risks are discussed in greater detail under the section entitled "*Risk Factors*" in this prospectus. Salarius and Decoy both encourage you to read and consider all of these risks carefully.

Implications of Being a Smaller Reporting Company

Salarius is a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Salarius may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of Salarius' voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of its second fiscal quarter or (ii) Salarius' annual revenue is less than $100 million during the most recently completed fiscal year and the market value of its voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of its second fiscal quarter. Specifically, as a smaller reporting company, Salarius may choose to present only the two most recent fiscal years of audited financial statements in its Annual Reports on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, as long as Salarius is a smaller reporting company with less than $100 million in annual revenue, its is not required to obtain an attestation report on internal control over financial reporting from its independent registered public accounting firm.

Salarius Corporate Information

Salarius was incorporated as Flex Pharma, Inc. ("Flex Pharma"), in Delaware in February 2014. In July 2019, Salarius' wholly owned subsidiary, Falcon Acquisition Sub, LLC, merged with and into Salarius Pharmaceuticals, LLC ("Private Salarius"), with Private Salarius becoming Salarius' wholly owned subsidiary, and Salarius changed its name to Salarius Pharmaceuticals, Inc. Salarius' principal executive offices are located at 2450 Holcombe Blvd., Suite X, Houston, Texas 77021 and its telephone number is (713) 913-5608. Salarius' website address is www.salariuspharma.com. Salarius does not incorporate the information on, or accessible through, Salarius' website into this prospectus, and Salarius should not consider any information on, or accessible through, Salarius' website as part of this prospectus.

Salarius files annual, quarterly and current reports, proxy statements and other information with the U.S. Securities and Exchange Commission (the "SEC"). The SEC maintains an Internet website at *www.sec.gov* that contains reports, proxy and information statements and other information about issuers, like Salarius, that file electronically with the SEC. Salarius also maintains a website at *www.salariuspharma.com*. Salarius makes available, free of charge, on its investor relations website at *investors.salariuspharma.com*, its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports as soon as reasonably practicable after electronically filing or furnishing those reports to the SEC. Information contained on or accessible through Salarius' website is not a part of or incorporated by reference into this prospectus and the inclusion of Salarius' website and investor relations website addresses in this prospectus is an inactive textual reference only.

SELECTED HISTORICAL AND UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL DATA

The following tables present summary historical financial data for Decoy, summary unaudited pro forma condensed combined financial data for Salarius and Decoy, and comparative historical and unaudited pro forma per share data for Salarius and Decoy.

Selected Historical Financial Data of Salarius

The following selected statement of operations data for the years ended December 31, 2023 and 2022 and the selected balance sheet data as of December 31, 2023 and 2022 was derived from Salarius' audited financial statements included elsewhere in this prospectus. The following selected financial data as of and for the nine months ended September 30, 2024 and 2023 are derived from Salarius' unaudited condensed financial statements included in this prospectus.

Salarius' historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected financial data below in conjunction with the section entitled "*Management's Discussion and*

Analysis of Financial Condition and Results of Operations of Salarius" and Salarius' financial statements and related notes appearing elsewhere in this prospectus.

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 5,899,910	$ 12,106,435
Grants receivable from CPRIT	—	1,610,490
Prepaid expenses and other current assets	619,763	803,373
Total current assets	6,519,673	14,520,298
Other assets	66,850	130,501
Total assets	$ 6,586,523	$ 14,650,799
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 602,853	$ 2,858,330
Accrued expenses and other current liabilities	406,745	1,407,861
Notes payable	289,643	$ —
Total liabilities	$ 1,299,241	$ 4,266,191
Commitments and contingencies (NOTE 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; none issued or outstanding	—	$ —
Common stock, $0.0001 par value; 100,000,000 shares authorized; 492,304 and 281,987shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	49	$ 28
Additional paid-in capital	81,635,074	$ 74,189,728
Accumulated deficit	(76,347,841)	$ (63,805,148)
Total stockholders' equity	5,287,282	$ 10,384,608
Total liabilities and stockholders' equity	$ 6,586,523	$ 14,650,799

	Twelve Months Ended December 31	
	2023	2022
Operating expenses:		
Research and development	7,173,747	15,836,828
General and administrative	5,721,197	7,138,403
Loss on impairment of goodwill	—	8,865,909
Total operating expenses	12,894,944	31,841,140
Loss before other income (expense)	(12,894,944)	(31,841,140)
Change in fair value of warrant liability	—	14,454
Interest income	352,251	218,730
Net loss	$ (12,542,693)	$ (31,607,956)
Loss attributable to common stockholders	$ (12,542,693)	$ (31,607,956)
Loss per common share — basic and diluted	$ (30.74)	$ (119.02)
Total net loss per share	$ (30.74)	$ (119.02)
Weighted-average number of common shares outstanding — basic and diluted	408,078	265,564

	Three Months Ended September 30		Nine Months Ended September 30	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 137,234	$ 1,036,354	$ 594,683	$ 7,113,794
General and administrative	869,237	1,495,831	3,650,920	4,810,449
Total operating expenses	1,006,471	2,532,185	4,245,603	11,924,243
Loss before other income (expense)	(1,006,471)	(2,532,185)	(4,245,603)	(11,924,243)
Interest income, net and other	34,350	89,369	133,759	263,346
Loss from continuing operations	**(972,121)**	**(2,442,816)**	**(4,111,844)**	**(11,660,897)**
Net loss	**$ (972,121)**	**$ (2,442,816)**	**$ (4,111,844)**	**$ (11,660,897)**
Loss per common share — basic and diluted [1]	**$ (0.76)**	**$ (5.21)**	**$ (5.13)**	**$ (30.71)**
Weighted-average number of common shares outstanding — basic and diluted [1]	1,281,869	469,254	801,395	379,693

(1) Share and per share amounts have been restated to reflect the 1-for-8 reverse stock split effected in June 14, 2024 on retroactive basis for all periods presented.

Selected Historical Financial Data of Decoy

The selected statement of operations data for the years ended December 31, 2023 and 2022 and the selected balance sheet data as of December 31, 2023 and December 31, 2022 are derived from Decoy's audited financial statements prepared using accounting principles generally accepted in the United States ("U.S. GAAP"), which are included in this prospectus. The selected statement of operations data for the nine months ended September 30, 2024 and 2023 and the selected balance sheet data as of September 30, 2024 and 2023 are derived from Decoy's unaudited condensed financial statements included in this prospectus. The financial data should be read in conjunction with the section entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations of Decoy*" and Decoy's financial statements and related notes appearing elsewhere in this prospectus. The historical results are not necessarily indicative of results to be expected in any future period.

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,156,433	$ 1,624,242
Prepaid expenses and other current assets	194,664	65,864
Total current assets	4,351,097	$ 1,690,106
Fixed assets, net of depreciation	105,450	140,758
Other assets - long term	41,000	40,280
Total assets	$ 4,497,547	$ 1,871,144
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 400,495	$ 434,462
Accrued expenses	185,024	59,501
Accrued interest and financing expense	1,541,863	408,257
Deferred income - grants	4,077,453	143,654
Promissory note	1,425,939	—
Convertible note - seed tranche A	4,122,000	1,381,000
Convertible note - seed	1,073,000	749,000
Convertible note - senior	6,523,556	4,038,000
Total current liabilities	19,349,330	7,213,874
Warrants	131,000	382,000
Total liabilities	$ 19,480,330	$ 7,595,874
Commitments and contingencies	—	—
Shareholders' equity:		
Preferred stock; par value $0.001 par value – 2,000,000 shares authorized -0- shares issued and outstanding at December 31, 2023 and 2022.	—	—
Common stock; par value $.001 per share; 6,000,000 shares authorized (includes 1,000,000 non-voting shares) at December 31, 2023 and 2022; 1,287,930 shares issued and outstanding at December 31, 2023 and 2022.	1,288	1,288
Additional paid in capital	74,512	4,026
Accumulated deficit	(15,058,583)	(5,730,044)
Total shareholders' equity (deficit)	$ (14,982,783)	$ (5,724,730)
Total liabilities and shareholders' equity	$ 4,497,547	$ 1,871,144

	Years Ended December 31,	
	2023	2022
Operating expenses		
General and administrative	$ 1,065,022	$ 1,024,835
Research and development	2,384,897	2,265,601
Total operating expenses	$ 3,449,919	$ 3,290,436
Other (income) and expenses		
Grant income	$ (666,201)	$ (738,990)
Fair value adjustment to convertible notes payable	5,643,000	703,000
Warrant liability (income) expense	(251,000)	108,000
Financing expense	52,556	22,500
Unrealized loss (gain)	—	(315)
Interest and financing expense	1,100,265	331,011
Total other (income) expense	5,878,620	425,206
Net loss	$ (9,328,539)	$ (3,715,643)
Net loss attributable to shareholders - per share		
Basic	$ (7.24)	$ (2.56)
Fully-diluted	$ (7.24)	$ (2.56)
Weighted average number of common shares		
Basic	1,287,930	1,449,292
Fully-diluted	1,287,930	1,449,292

	Nine months ended September 30,	
	2024	2023
Operating expenses		
General and administrative	$ 872,415	$ 710,971
Research and development	1,925,148	1,662,456
Total operating expenses	$ 2,797,563	$ 2,373,427
Other (income) and expenses		
Grant income	$ (1,134,817)	$ (307,997)
Fair value adjustment to convertible notes payable	406,000	2,604,000
Warrant liability (income) expense	174,465	—
Financing expense	97,007	28,993
Unrealized loss (gain)	517	—
Interest expense	913,093	1,231,402
Total other (income) expense	456,265	3,556,399
Net loss	$ (3,253,828)	$ (5,929,826)
Net loss attributable to shareholders - per share		
Basic	$ (2.53)	$ (4.60)
Fully-diluted	$ (2.53)	$ (4.60)
Weighted average number of common shares		
Basic	1,287,930	1,287,930
Fully-diluted	1,287,930	1,287,930

Selected Unaudited Pro Forma Condensed Combined Financial Data of Salarius and Decoy

The following selected unaudited pro forma consensed combined balance sheet as of September 30, 2024 combines the historical consolidated balance sheet of Salarius as of September 30, 2024 with the historical balance sheet of Decoy as of September 30, 2024 giving further effect to the pro forma adjustments described in Note 5 to the "*Notes To The Unaudited Pro Forma Consolidated Combined Financial Information*" included in this prospectus, as if they had been consummated as of September 30, 2024.

The following unaudited pro forma consolidated combined statements of operations for the year ended December 31, 2023 combine the historical consolidated statement of operations of Salarius for the year ended December 31, 2023 and the historical statements of operations of Decoy for the year ended December 31, 2023, giving effect to the pro forma adjustments described in Note 5 to the "*Notes To The Unaudited Pro Forma Consolidated Combined Financial Information*" included in this prospectus, as if they had been consummated on January 1, 2023, the beginning of the earliest period presented.

The following unaudited pro forma consolidated combined statements of operations for the nine months ended September 30, 2024 combine the historical consolidated statement of operations of Salarius for the nine months ended September 30, 2024 and the historical statements of operations of Decoy for the nine months ended September 30, 2024, giving effect to the pro forma adjustments described in Note 5 to the "*Notes To The Unaudited Pro Forma Consolidated Combined Financial Information*" included in this prospectus, as if they had been consummated on January 1, 2023, the beginning of the earliest period presented.

The unaudited pro forma consolidated combined financial statements have been derived from and should be read in connection with:

- the accompanying notes to the unaudited pro forma consolidated combined financial statements;
- the historical unaudited consolidated financial statements of Salarius as of and for the nine months ended September 30, 2024 and the related notes included in this prospectus;
- the historical unaudited financial statements of Decoy as of and for the nine months ended September 30, 2024 and the related notes included in this prospectus;
- the historical audited consolidated financial statements of Salarius as of and for the year ended December 31, 2023 and the related notes included in this prospectus;
- the historical audited financial statements of Decoy as of and for the year ended December 31, 2023 and the related notes included this prospectus;
- the sections entitled *"Salarius Management's Discussion and Analysis of Financial Condition and Results of Operations of Salarius," "Management's Discussion and Analysis of Financial Condition and Results of Operations of Decoy,"* and other financial information relating to Salarius and Decoy.

The unaudited pro forma consolidated combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The accounting for the Merger requires the financial calculation of Salarius' net cash. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing unaudited pro forma consolidated combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the Closing of the Merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma consolidated combined financial information and the combined company's future results of operations and financial position.

The unaudited pro forma combined consolidated financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma consolidated combined financial information is not necessarily indicative of the financial position or results of operations in the future periods or the result that actually would have been realized had Salarius and Decoy been a combined organization during the specified periods. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited consolidated combined pro forma financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma consolidated combined financial information.

	Historical						
	Decoy	Salarius	Financing Transaction Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
Asset							
Current assets:							
Cash and cash equivalents	3,199	3,284	6,194	(a)	(1,729)	(b) (f)	10,948
Prepaid expenses and other current assets	182	539	—		—		721
Total Current Assets	3,381	3,823	6,194		(1,729)		11,669
Fixed asset, net	71	—	—		—		71
Other assets	40	36	—		—		76
Total assets	3,492	3,859	$ 6,194		(1,729)		11,816
Liabilities, convertible preferred stock and stockholders' equity (deficit)							
Current liabilities:							
Accounts Payable	837	166	$ —		$ —		1,003
Accrued expenses and other current liabilities	308	440	—		156	(c)	904
Notes payable	—	329	—		—		329
Accrued interest and financing expense	2,377	—	—		(2,377)	(d)	—
Deferred income - grants	3,193	—	—		—		3,193
Shareholder notes payable	118	—	—		(118)	(d)	—
Promissory notes payable	2,151	—	—		(2,151)	(d)	—
Convertible note – seed Tranche A	4,382	—	—		(4,382)	(d)	—
Convertible note - seed	1,093	—	—		(1,093)	(d)	—
Convertible note - senior	6,746	—	—		(6,746)	(d)	—
Total Current Liabilities	21,205	935	—		(16,711)		5,429
Warrants	305	—	—		(305)	(d)	—
Total liabilities	21,510	935	—		(17,016)		5,429
Stockholders' equity (deficit):							
Salarius preferred stock; $0.0001 par value;	—	—	—		1	(e)	1
Decoy common stock, $0.00001 par value	1	—	—		(1)	(e)	—
Salarius common stock	—	—	1		—	(d) (e)	1
Additional paid-in capital	293	83,384	6,193	(a)	(63,968)	(d) (e) (f)	25,902
Accumulated deficit	(18,312)	(80,460)	—		79,255	(b) (c) (f)	(19,517)
Total stockholders' equity (deficit)	(18,018)	2,924	6,194		15,287		6,387
Total liabilities, convertible preferred stock and stockholders' equity	3,492	3,859	$ 6,194		(1,729)		11,816

THE OFFERING

Common stock Salarius is offering	shares of Salarius' common stock (or shares of Salarius' common stock if the underwriters exercise the over-allotment option in full).
Public offering price	Salarius has assumed a public offering price of $ per share of common stock, which represents the last reported sale price of Salarius' common stock as reported on The Nasdaq Capital Market on , 2025. The final public offering price will be determined through negotiation between Salarius and the underwriters in the offering and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.
Pre-funded warrants Salarius is offering	Salarius is also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of Salarius' outstanding common stock immediately following the closing of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded warrants to purchase shares of Salarius' common stock, in lieu of shares of common stock that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of Salarius' outstanding common stock. Each pre-funded warrant is exercisable for one share of Salarius' common stock. The purchase price of each pre-funded warrant is equal to the price at which a share of common stock is being sold to the public in this offering, minus $0.0001, and the exercise price of each pre-funded warrant is $0.0001 per share. The pre-funded warrants are exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded warrant that Salarius sells, the number of shares of common stock that Salarius is offering will be reduced on a one-for-one basis.
Over-allotment option	The underwriters have the option to purchase an aggregate of additional shares of common stock solely to cover over-allotments, if any, at the price to the public less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of Salarius' common stock as determined by the underwriters. The over-allotment option is exercisable for forty-five (45) days from the date of this prospectus.
Representative Warrants	Salarius has agreed to issue to the representative warrants, or the "representative warrants," to purchase up to shares of common stock (or shares of common stock assuming the exercise of the over-allotment option in full) as a portion of the compensation payable to the representative in connection with this offering. The representative warrants will be immediately exercisable upon issuance at an exercise price equal to $ per share of common stock and will expire on the fifth anniversary of the commencement of sales of this offering. The representative warrants and the shares of common stock underlying the representative warrants are being registered on the registration statement of which this prospectus is a part. See "*Underwriting*" on page 185 for more information.
Common stock outstanding immediately before this offering	shares of Salarius' common stock

Common stock outstanding immediately after this offering	shares of Salarius' common stock (or shares if the underwriters exercise the over-allotment option in full, and assuming no sale of any pre-funded warrants and assuming none of the representative warrants issued in this offering are exercised.
Use of Proceeds	Salarius estimates that the net proceeds to Salarius from this offering will be approximately $ million (or $ million if the underwriters exercise the over-allotment option in full), after deducting the underwriting discounts and commissions and estimated offering expenses payable by Salarius. Salarius intends to use the net proceeds from this offering primarily for general corporate purposes, including working capital, research and development, and capital expenditures. See "*Use of Proceeds*" for additional information.
Risk Factors	An investment in Salarius' common stock involves a high degree of risk. See the information contained in "*Risk Factors*" on page 25 of this prospectus.
The Nasdaq Capital Market symbol	Salarius' common stock is listed on The Nasdaq Capital Market under the symbol "SLRX." There is no established trading market for the pre-funded warrants and Salarius does not expect a market to develop. In addition, Salarius does not intend to apply for the listing of the pre-funded warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Outstanding Shares

The number of shares of Salarius' common stock to be outstanding after this offering is based on 1,583,567 shares of Salarius' common stock outstanding as of January 14, 2025, plus (i) an estimated shares of common stock be issued to the Decoy stockholders at the Merger Closing assuming no adjustment to the exchange ratio at Merger Closing, and (ii) an estimated shares of Series A Preferred Stock to be issued at the Merger Closing assuming conversion of all such shares of Series A Preferred Stock into common stock at a ratio of 1:1,000, and excludes:

- 31,554 shares of Salarius' common stock issuable upon the exercise of stock options outstanding as of January 14, 2025 at a weighted-average exercise price of $66.75 per share;
- 131 shares of Salarius' common stock issuable upon the settlement of restricted stock units outstanding as of January 14, 2025;
- 106,293 shares of Salarius' common stock issuable upon the exercise of warrants outstanding as of January 14, 2025 at a weighted average exercise price of $133 per share;
- 67,490 shares of Salarius' common stock available for future issuance under the 2015 Equity Incentive Plan as of January 14, 2025;
- 54,324 shares of Salarius' common stock reserved for future issuance under the 2015 Employee Stock Purchase Plan as of January 14, 2025; and
- shares of Salarius' common stock issuable upon the exercise of the representative warrants issued as compensation to the representative in this offering.

Except as otherwise noted, all information in this prospectus assumes:

- no issuance of shares pursuant to the ELOC Agreement after January 14, 2025;

- no issuance of shares pursuant to that certain At the Market Offering Agreement, dated February 5, 2021, between Salarius and Ladenburg Thalmann & Co. Inc. after January 14, 2025;
- no exercise of the outstanding existing warrants and options or vesting of the outstanding restricted stock units described above, in each case, after January 14, 2025;
- no exercise of outstanding equity awards pursuant to any Decoy equity incentive plans to be assumed by Salarius in connection with the Merger; and
- the exercise for cash of all pre-funded warrants in this offering.

RISK FACTORS

Investing in Salarius' securities involves a high degree of risk. In addition to the risk factors and uncertainties relating to Salarius that are included herein, in connection with Salarius' proposed Merger with Decoy you should consider the following additional risks and uncertainties that could affect the post-Merger combined company and materially affect the combined company's business, results of operations or financial condition and cause the value of Salarius' securities to decline. If any of these risks occur, Salarius' business, financial condition, results of operations, and future prospects would likely be materially and adversely affected. In these circumstances, the market price of Salarius' common stock and value of Salarius' other securities would likely decline and you may lose all or part of your investment. Share information set forth in these risk factors is as of the dates set forth herein or therein and unless otherwise indicated, does not give effect to the issuance of the securities in connection with this offering.

Risks Related to the Merger

The Merger may be completed even though certain events occur prior to Merger Closing that materially and adversely affect Salarius or Decoy.

The Merger Agreement provides that either Salarius or Decoy can refuse to complete the Merger if there is a material adverse change affecting the other party between January 10, 2025, the date of the Merger Agreement, and the Merger Closing. However, certain types of changes do not permit either party to refuse to complete the Merger, even if such change could be said to have a material adverse effect on Salarius or Decoy, including:

- general business or economic conditions affecting the industry in which Salarius or Decoy or their subsidiaries, as applicable, operate;
- acts of war, armed hostilities or terrorism, acts of God or comparable events, epidemic, pandemic or disease outbreak (including the COVID-19 virus) or any worsening of the foregoing, or any declaration of martial law, quarantine or similar directive, policy or guidance or law or other action by any governmental body in response thereto;
- changes in financial, banking or securities markets;
- any change in, or any compliance with or action taken for the purpose of complying with, any law or generally accepted accounting principles ("GAAP") (or interpretations of any law or GAAP);
- changes resulting from the announcement of the Merger Agreement or the pendency of the transactions contemplated by the Merger Agreement; or
- changes resulting from the taking of any action required to be taken under the Merger Agreement.

If adverse changes occur and Salarius and Decoy still complete the Merger, the market price of the combined company's common stock may suffer. This in turn may reduce the value of the Merger to the stockholders of Salarius, Decoy or participants in this offering.

The Exchange Ratio set forth in the Merger Agreement is adjustable based on the Parent Cash Amount and the Company Cash Amount, each of which will be impacted by, among other things, unexpected expenses that could be experienced by Salarius or Decoy during the pre-Merger Closing period, which could result in Salarius stockholders owning significantly less of the combined company than currently estimated.

The Exchange Ratio formula in the Merger Agreement is subject to adjustment based on the Parent Cash Amount and Company Cash Amount on the anticipated Merger Closing Date (each as defined in the Merger Agreement). For example, if the Parent Cash Amount is $0 and the Company Cash Amount is $2.0 million, stockholders of Salarius would own approximately 14.1% of the fully diluted common stock, and stockholders of Decoy would own, or hold rights to acquire, approximately 85.9% of Salarius common stock, in each case calculated on a fully-diluted basis for in-the-money options and warrants (and in each case, prior to taking into account any dilution from the Qualified Financing). The calculation of the Exchange Ratio under the Merger

Agreement and post-Merger Closing ownership of Salarius stockholders are subject to adjustment based on an assumed value of Salarius at Merger Closing based on the Parent Cash Amount and Company Cash Amount as of the anticipated Merger Closing Date. To the extent the Parent Cash Amount falls below $0, Salarius' assumed value would be reduced or increased by $100,000 for every $100,000 below the threshold. To the extent the Company Cash Amount falls below $2.0 million, Decoy's assumed value would be reduced by $100,000 for every $100,000 below the threshold.

Based on Salarius' current estimates, Salarius anticipates delivering a Parent Cash Amount of approximately $0; however, the final Parent Cash Amount will not be calculated until the anticipated Merger Closing Date, and may vary significantly depending on, among other things, Salarius' ability to control and correctly estimate its operating expenses, and if the amount is significantly less, Salarius stockholders would experience additional dilution, subject to a floor of 10% of the combined company, regardless of the Parent Cash Amount on the anticipated Merger Closing Date. Further, these ownership percentages do not give effect to the shares of Salarius common stock that will be issued to investors in the Qualified Financing prior to the Merger Closing, and do not account for any additional shares of Salarius common stock that may be issued to investors following the effective time of the Merger. As a result, stockholders of Salarius and/or Decoy could own less of the combined company than currently contemplated.

Stockholders of the combined company may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger and the Qualified Financing.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, Salarius stockholders and Decoy stockholders will have experienced substantial dilution of their ownership interests in their respective companies. The Qualified Financing may cause substantial dilution to Salarius and Decoy stockholders which may result in such stockholders not receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Qualified Financing.

The historical unaudited pro forma condensed combined financial information may not be representative of the combined company's results after the Merger.

The historical unaudited pro forma condensed combined financial information included elsewhere in this prospectus has been presented for informational purposes only and is not necessarily indicative of the financial position or results of operations that actually would have occurred had the Merger been completed as of the date indicated, nor is it indicative of future operating results or financial position.

During the pendency of the Merger, Salarius and Decoy may not be able to enter into a business combination with another party at a favorable price because of restrictions in the Merger Agreement, which could adversely affect their respective businesses.

Covenants in the Merger Agreement impede the ability of Salarius and Decoy to make acquisitions, subject to certain exceptions relating to fiduciary duties, as set forth below, or to complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, the parties may be at a disadvantage to their competitors during such period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, initiating, encouraging or entering into certain extraordinary transactions, such as a merger, sale of assets, or other business combination outside the ordinary course of business with any third party, subject to certain exceptions relating to fiduciary duties. Any such transactions could be favorable to such party's stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of Salarius and Decoy from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when such party's board of directors determines in good faith that an unsolicited alternative takeover proposal is or is reasonably likely to lead to a superior takeover proposal and that failure to cooperate with the proponent of the

proposal would be reasonably likely to be inconsistent with the applicable board's fiduciary duties. Any such transactions could be favorable to such party's stockholders. In addition, if Salarius terminates the Merger Agreement under certain circumstances, including terminating because of a decision of Salarius to enter into definitive agreement with respect to a superior offer, Salarius would be required to pay a termination fee of $300,000 to Decoy. This termination fee described above may discourage third parties from submitting alternative takeover proposals to Salarius stockholders.

Pursuant to the terms of the Merger Agreement, Salarius is required to recommend that its stockholders approve the conversion of all outstanding shares of its Series A Preferred Stock into shares of its Common Stock. Salarius cannot guarantee that its stockholders will approve this matter, and if they fail to do so its operations may be materially harmed.

Under the terms of the Merger Agreement, Salarius agreed following the consummation of the Merger to use reasonable best efforts to call and hold a meeting of Salarius stockholders to obtain the requisite approval for the conversion of all outstanding shares of Series A Preferred Stock issued in the Merger into shares of Salarius Common Stock, as required by the Nasdaq listing rules, as soon as practicable after the Merger Closing of the Merger and, if such approval is not obtained at that meeting, to seek to obtain such approval at an annual or special stockholders meeting to be held at least every four months thereafter until such approval is obtained, which would be time-consuming and costly and could significantly negatively affect Salarius' projected cash position.

Because the lack of a public market for Decoy's capital stock makes it difficult to evaluate the value of Decoy's capital stock, the stockholders of Decoy may receive shares of Salarius common stock in the Merger that have a value that is greater than, the fair market value of Decoy's capital stock.

The outstanding capital stock of Decoy is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Decoy. Because the percentage of Salarius common stock to be issued to Decoy's stockholders was determined based on negotiations between the parties, it is possible that Salarius may pay more than the aggregate fair market value for Decoy.

The combined company may become involved in securities class action litigation that could divert management's attention and harm the combined company's business and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action or shareholder derivative litigation often follows certain significant business transactions, such as the sale of a business division or announcement of a merger. The combined company may become involved in this type of litigation in the future. Litigation is often expensive and diverts management's attention and resources, which could adversely affect the combined organization's business.

The Merger Agreement between Salarius and Decoy may be terminated in accordance with its terms and the Merger may not be completed.

The Merger Agreement is subject to a number of conditions which must be fulfilled in order to complete the Merger. Those conditions include, among other things: (i) the lack of a Material Adverse Effect on the respective businesses of Salarius and Decoy; (ii) the continued listing of Salarius' Common Stock on The Nasdaq Capital Market ("Nasdaq") through the Merger Closing; (iii) the absence of any order, injunction, decree or other legal restraint preventing the consummation of the Merger or any of the other transactions contemplated by the Merger Agreement or making the completion of the Merger or any of the other transactions contemplated by the Merger Agreement illegal; (iv) completion of the Qualified Financing and (v) the accuracy of the respective parties' representations and warranties contained in the Merger Agreement (subject to certain customary qualifications) and compliance by Salarius and Decoy with its respective agreements and covenants contained in the Merger Agreement.

These conditions to the Merger Closing may not be fulfilled in a timely manner or at all, and, accordingly, the Merger may not be completed. In addition, the parties can mutually decide to terminate the Merger Agreement at any time, or Salarius or Decoy may elect to terminate the Merger Agreement in certain other circumstances.

Salarius may not be able to effect the Merger pursuant to the Merger Agreement, and failure to complete the Merger could negatively impact Salarius' stock price and the future business and financial results of the Salarius.

In connection with the Merger Agreement, Salarius has incurred substantial costs planning and negotiating the transaction. These costs include, but are not limited to, costs associated with employing and retaining third-party advisors who performed the financial, auditing, and legal services required before Salarius was able to enter into the Merger Agreement and which will continue as Salarius seeks to complete the transaction. If, for whatever reason, including those set forth above, the transactions contemplated by the Merger Agreement fail to close, Salarius' will be responsible for these costs, which could adversely affect Salarius liquidity and financial results. In addition, Salarius' stock price may decline significantly if the Merger is not completed.

The market price of Salarius' common stock following the Merger may decline as a result of the Merger.

The market price of Salarius' common stock may decline as a result of the Merger for a number of reasons, including if:

- investors react negatively to the prospects of the combined company's product candidates, business and financial condition following the Merger;
- the effect of the Merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts.

Salarius and Decoy securityholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the Merger Closing as compared to their current ownership and voting interest in the respective companies.

If the proposed Merger is completed, the current securityholders of Salarius and Decoy will own a smaller percentage of the combined company than their ownership in their respective companies prior to the Merger. Accordingly, the issuance of shares of Salarius common stock to Decoy's stockholders in the Merger will reduce significantly the relative voting power of each share of Salarius common stock held by its current stockholders and will reduce the relative voting power of each share of Decoy common stock held by its current stockholders. Consequently, Salarius' stockholders as a group and Decoy's stockholders as a group will have less influence over the management and policies of the combined company after the Merger than prior to the Merger.

Consequently, securityholders of both Salarius and Decoy will be able to exercise less influence over the management and policies of the combined company following the Merger Closing than they currently exercise over the management and policies of their respective companies.

The combined company will need to raise additional capital by issuing securities or debt or through licensing or other strategic arrangements, which may cause dilution to the combined company's stockholders or restrict the combined company's operations or impact its proprietary rights.

The combined company may be required to raise additional funds sooner than currently planned. If either or both of Salarius or Decoy hold less cash at the time of the Merger Closing than the parties currently expect, the combined company will need to raise additional capital sooner than expected. Additional financing may not be available to the combined company when it needs it or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such an issuance may cause significant dilution to the combined company's stockholders' ownership and the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing the combined company enters into may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to create liens, pay dividends, redeem its stock or make investments. In addition, if the combined company

raises additional funds through licensing, partnering or other strategic arrangements, it may be necessary to relinquish rights to some of the combined company's technologies or product candidates and proprietary rights, or grant licenses on terms that are not favorable to the combined company.

Furthermore, provisions in the agreements for the Qualified Financing may deter or prevent the combined company from raising additional capital to fund the company as and when needed. Restrictive covenants and other provisions in the Qualified Financing documents could deter or prevent the combined company from raising additional capital as and when needed. The combined company's failure to raise capital as and when needed would have a negative effect on its financial condition and its ability to develop and commercialize its pipeline and otherwise pursue the combined company's business strategy and the combined company may be unable to continue as a going concern.

Risks Related to this Offering

You will experience immediate and substantial dilution if you purchase Salarius' securities in this offering.

Since the price per share of Salarius' common stock and the price per pre-funded warrant being offered is substantially higher than the pro forma net tangible book value per share of Salarius' common stock, you will suffer substantial dilution with respect to the securities you purchase in this offering. Salarius' net tangible book value as of September 30, 2024 was approximately $2.9 million, or $2 per share of Salarius' common stock, based on 1,441,157 shares of Salarius' common stock outstanding on September 30, 2024. Salarius' pro forma net tangible book value as of September 30, 2024 was approximately $ million, or $ per share of Salarius' common stock, based on 1,441,157 shares of Salarius' common stock outstanding on September 30, 2024, plus shares of Salarius' common stock issued after September 30, 2024 to , 2025.

After giving effect to the sale of (i) shares of Salarius' common stock in this offering at the offering price of $ per share and (ii) pre-funded warrants to purchase shares of Salarius' common stock in this offering at the offering price of $ per pre-funded warrant (which equals the price per share at which shares of Salarius' common stock are being sold in this offering, minus the $0.0001 per share exercise price of each such pre-funded warrant), including shares of common stock issuable upon exercise of the pre-funded warrants but excluding any resulting accounting associated therewith, and after deducting underwriting discounts and commissions and estimated offering expenses payable by Salarius in connection with this offering, Salarius' pro forma as-adjusted net tangible book value as of September 30, 2024 would have been approximately $ million, or approximately $ per share of Salarius' common stock. As a result, investors purchasing securities in this offering will incur immediate dilution of $ per share. As a result of the dilution to investors purchasing shares in this offering, investors in this offering may receive significantly less than the purchase price paid in this offering, if anything, in the event of Salarius' liquidation. See the section entitled "Dilution" on page 67 of this prospectus for a more detailed discussion of the dilution you will incur if you purchase shares of Salarius' common stock or pre-funded warrants in this offering.

In addition, as of January 14, 2025, Salarius had outstanding options to purchase 31,554 shares of its common stock at a weighted-average exercise price of $66.75 per share, outstanding restricted stock units to acquire 131 shares of Salarius' common stock and outstanding warrants to purchase 106,293 shares of Salarius' common stock at a weighted-average exercise price of $133. As of January 14, 2025, there were 67,490 shares of Salarius' common stock available for future issuance under Salarius' 2015 Equity Incentive Plan (the "2015 Equity Incentive Plan") and 54,324 shares of Salarius' common stock available for future issuance under Salarius' 2015 Employee Stock Purchase Plan (the "2015 Employee Stock Purchase Plan"). The shares of Salarius common stock issuable under the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan may be immediately eligible for resale in the open market. Such shares of Salarius common stock, along with any other market transactions, could adversely affect the market price of Salarius common stock. Additional dilution may result from the issuance of shares of Salarius common stock in connection with additional financings or in connection with commercial transactions.

Substantial future sales or other issuances of Salarius common stock could depress the market for Salarius' common stock.

In the future, sales of a substantial number of shares of Salarius common stock, or the perception by the market that those sales could occur, could cause the market price of Salarius' common stock to decline or could make it more difficult for Salarius to raise funds through the sale of equity in the future.

In connection with this offering, Salarius and its directors and executive officers expect to enter into lock-up agreements for a period of days. Salarius and its directors and executive officers may be released from such lock-up agreements prior to the expiration of the lock-up period at the sole discretion of the representative. Upon expiration or earlier release of the lock-up, Salarius and its directors and executive officers may sell shares into the market, which could adversely affect the market price of shares of Salarius' common stock.

Salarius has previously entered into an At the Market Offering Agreement dated as of February 5, 2021, with the representative, pursuant to which, from time to time, Salarius may offer and sell shares of its common stock under an "at-the-market" offering program. To the extent that Salarius sells shares of its common stock pursuant to the at-the-market offering program or any similar program in the future, investors purchasing shares of Salarius' common stock in this offering could experience further dilution.

Salarius has also previously entered into that certain Securities Purchase Agreement dated December 12, 2024, by and between C/M Capital Master Fund, LP and Salarius (the "ELOC Agreement") pursuant to which, from time to time, Salarius may sell up to $10 million of shares of its common stock to C/M Capital Master Fund, LP at various prices. To the extent that Salarius sells shares of its common stock pursuant to the agreement, investors purchasing shares of Salarius' common stock in this offering could experience further dilution.

Future issuances of Salarius common stock or its other equity securities could further depress the market for Salarius' common stock. Salarius expects to continue to incur drug development and selling, general and administrative costs, and to satisfy its funding requirements, Salarius may need to sell additional equity securities. The sale or the proposed sale of substantial amounts of Salarius common stock or its other equity securities may adversely affect the market price of Salarius' common stock and Salarius' stock price may decline substantially. Salarius' stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. New equity securities issued may have greater rights, preferences or privileges than Salarius' existing common stock.

Salarius has broad discretion in how it uses the proceeds of this offering and may not use these proceeds effectively, which could affect Salarius' results of operations and cause its common stock to decline.

Salarius currently intends to use the net proceeds from this offering for general corporate purposes, including working capital, research and development, and capital expenditures. A portion of the net proceeds may also be used to acquire, license or invest in complementary products, technologies, intellectual property or businesses, although Salarius has no present commitments or agreements to do so. However, Salarius has not determined the specific allocation of the net proceeds among these potential uses. Salarius' management will have broad discretion over the use and investment of the net proceeds from this offering, and, accordingly, investors in this offering will need to rely upon the judgment of its management with respect to the use of proceeds, with only limited information concerning Salarius' specific intentions. These proceeds could be applied in ways that do not improve Salarius' operating results or increase the value of your investment. See the section entitled "Use of Proceeds" on page 62 of this prospectus for further information about the use of proceeds.

Salarius does not currently intend to pay dividends on its common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of Salarius common stock.

Salarius has never declared or paid cash dividends on its capital stock, and you should not rely on an investment in Salarius' common stock to provide dividend income. Salarius currently intends to retain all of its future earnings, if any, to finance the growth and development of its business and does not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of Salarius common stock will be your sole source of gain for the foreseeable future.

The trading price of the shares of Salarius' common stock could be highly volatile, and purchasers of Salarius' common stock could incur substantial losses.

The price of Salarius' common stock is highly volatile and may be affected by developments directly affecting its business, as well as by developments out of its control or not specific to Salarius. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including Salarius', can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, Salarius' performance. This volatility may affect the price at which you could sell the shares of Salarius common stock, and the sale of substantial amounts of Salarius common stock could adversely affect the price of Salarius common stock. Salarius' stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including those described in the sections entitled "Risk Factors" in this prospectus.

As a result, you may not be able to sell your shares of common stock at or above the price at which you purchase them. In addition, the stock market in general, Nasdaq and the stock of pharmaceutical and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of Salarius' common stock, regardless of its actual operating performance.

There is no public market for the pre-funded warrants being offered in this offering.

There is no public trading market for the pre-funded warrants being offered in this offering, and Salarius does not expect a market to develop. In addition, Salarius does not intend to list the pre-funded warrants on Nasdaq or any other national securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Holders of the pre-funded warrants will have no rights as common stockholders until such holders exercise their pre-funded warrants and acquire Salarius common stock.

Except by virtue of such holder's ownership of shares of Salarius common stock, until holders of the pre-funded warrants exercise their pre-funded warrants and acquire shares of Salarius common stock, such holders will have no rights with respect to the shares of Salarius common stock underlying such pre-funded warrants.

Salarius may not receive any additional funds upon the exercise of the pre-funded warrants.

Each pre-funded warrant may be exercised by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of Salarius common stock determined according to the formula set forth in the pre-funded warrant. Accordingly, Salarius may not receive any additional funds upon the exercise of the pre-funded warrants.

Significant holders or beneficial holders of Salarius common stock may not be permitted to exercise pre-funded warrants that they hold.

A holder of a pre-funded warrant will not be entitled to exercise any portion of any pre-funded warrant which, upon giving effect or immediately prior to such exercise, would cause (i) the aggregate number of shares of Salarius common stock beneficially owned by such holder (together with its affiliates) to exceed 4.99% or 9.99% (at the initial election of the holder) of the number of shares of Salarius common stock outstanding immediately after giving effect to the exercise; or (ii) the combined voting power of Salarius' securities beneficially owned by such holder (together with its affiliates) to exceed 4.99% or 9.99% (at the initial election of the holder) of the combined voting power of all of Salarius' securities outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Such percentage may be increased by the holder of the pre-funded warrant to any other percentage not in excess of 9.99% of the issued and outstanding shares of Salarius' common stock immediately after giving effect to such issuance upon at least 61 days' prior notice from the holder to Salarius. As a result, you may not be able to exercise your pre-funded

warrants for shares of Salarius' common stock at a time when it would be financially beneficial for you to do so. In such circumstance you could seek to sell your pre-funded warrants to realize value, but you may be unable to do so in the absence of an established trading market for the pre-funded warrants.

Risks Related to Salarius

Risks Related to Salarius' Financial Position and Capital Needs

If the Merger is not completed, Salarius may not be able to otherwise source adequate liquidity to fund its operations, meet its obligations, and continue as a going concern. Salarius' board of directors may decide to pursue a dissolution and liquidation of Salarius. In such an event, there can be no assurances as to the amount or timing of available cash left, if any, to distribute to its stockholders after paying its debts and other obligations and setting aside funds for reserves.

While Salarius has entered into the Merger Agreement with Decoy, the Merger Closing may be delayed or may not occur at all and there can be no assurance that the Merger will deliver the anticipated benefits Salarius expects or enhance stockholder value. If the Merger is not completed and the Merger Agreement is terminated under certain circumstances, Salarius may be required to pay Decoy a termination fee of $300,000. Even if a termination fee is not payable in connection with a termination of the Merger Agreement, Salarius will have incurred significant fees and expenses, which must be paid whether or not the Merger is completed.

Salarius does not currently have adequate financial resources to fund its forecasted operating costs for at least twelve months from the filing of this prospectus. As of September 30, 2024, Salarius' cash and cash equivalents totaled $3.3 million, which were held in bank deposit accounts and a money market account. As of September 30, 2024, Salarius has incurred an accumulated deficit of $80.5 million. For the nine months ended September 30, 2024, Salarius reported net losses of $4.1 million. As of December 31, 2024, Salarius estimates that its cash and cash equivalents totaled $2.4 million, which were held in bank deposit accounts and a money market account. As a result, Salarius believes its existing cash resources are sufficient to meet its anticipated needs into the first half of 2025. If for any reason the Merger does not close, Salarius would need to raise additional capital to continue to fund the further development of its product candidates and its operations thereafter. Salarius has based its cash sufficiency estimates on its current business plan and its assumptions may prove to be wrong. Salarius could utilize its available capital resources sooner than it currently expects, and it could need additional funding sooner than currently anticipated. Additionally, the process of advancing early stage product candidates and testing product candidates in clinical trials is costly, and the timing of progress in these clinical trials is uncertain. Even if Salarius raises sufficient funds and decides to continue the development of its product candidates, its ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support its cost structure. Salarius cannot assure you that it will ever be profitable or generate positive cash flow from operating activities.

Failure to secure any necessary financing in a timely manner and on favorable terms or the failure of the proposed Merger to be consummated in a timely manner would require Salarius to further delay or abandon clinical development plans. If, for any reason, the Merger does not close, the Salarius board of directors may elect to, among other things, attempt to complete another strategic transaction like the Merger, attempt to sell or otherwise dispose of the various assets of Salarius, resume its research and development activities and continue to operate the business of Salarius. Any of these alternatives would be costly and time-consuming and would require that Salarius obtain additional funding. Salarius expects that it would be difficult to secure financing in a timely manner, on favorable terms or at all. Salarius can make no assurances that it would be able to obtain additional financing or find a partner and close an alternative transaction on terms that are as favorable or more favorable than the terms set forth in the Merger Agreement or that any such alternatives are possible or would be successful, if pursued. To the extent that Salarius seeks and is able to raise additional capital through the sale of equity or convertible debt securities, Salarius' stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting Salarius' ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If Salarius raises funds through strategic transactions or marketing, distribution, or licensing arrangements with third parties, Salarius may have to relinquish valuable rights to its technologies, future revenue streams, research programs or

product candidates or to grant licenses on terms that may not be favorable to it. Even if Salarius is able to pursue such alternatives, the failure to complete the Merger may result in negative publicity and/or a negative impression of Salarius in the investment community, could significantly harm the market price of Salarius common stock and may affect Salarius' relationship with employees and other partners in the business community.

If the Salarius board of directors were to decide to dissolve and liquidate Salarius' assets, Salarius would be required to pay all of its debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left, if any, to distribute to stockholders after paying its debts and other obligations and setting aside funds for reserves. In addition, Salarius may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, the Salarius board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, Salarius' stockholders would likely lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of Salarius.

Salarius does not believe that its current expenses are indicative of the costs it may incur in the future in connection with the development and commercialization of any product candidate if it consummates the Merger or raises additional capital to continue its operations. Salarius' future funding requirements will depend on many factors, including:

- its ability to consummate the Merger with Decoy;
- the scope, rate of progress and cost of its preclinical and clinical trials for any product candidate in its future pipeline and results of future clinical trials;
- the cost and timing of regulatory filings and approvals for any product candidates that successfully complete clinical trials;
- the timing and nature of any strategic transactions that Salarius undertakes, including potential partnerships;
- the effect of competing technological and market developments;
- the cost incurred in responding to actions by activist stockholders; and
- the cost of filing, prosecuting, defending and enforcing its intellectual property rights.

In addition, the amounts available under Salarius' shelf registration statement on Form S-3 will be significantly limited as long as Salarius' public float remains below $75 million, which, given its currently depressed stock price, limits its ability to obtain meaningful funding through a shelf registration statement at this time, although Salarius could still raise funds through a registration statement on Form S-1 or through private placements.

As such, there is uncertainty regarding Salarius' ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt about its ability to continue as a going concern.

Salarius' common stock may be subject to delisting from Nasdaq.

Salarius' common stock is currently listed on the Nasdaq Capital Market ("Nasdaq"). To maintain its listing on Nasdaq, Salarius is required to maintain: (i) a minimum bid price of $1.00 per share; (ii) a market value of publicly held securities of $1 million; (iii) a certain number of round lot stockholders; and (iv) one of the following: a net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or a stockholders' equity of at least $2.5 million (the "Stockholders' Equity Requirement"). Nasdaq has the authority to delist Salarius' common stock if Salarius fails to maintain these minimum requirements. In addition, Nasdaq may delist Salarius if, based on Nasdaq's review of Salarius' operations and pursuant to Nasdaq Listing Rule 5101, Nasdaq believes that Salarius is a "public shell" and that the continued listing of its securities is no longer warranted. Salarius has no current plans to delist its shares of common stock from Nasdaq. However, following the decision to close the clinical development of seclidemstat for Ewing sarcoma, Salarius may be treated as a public shell under Nasdaq rules. Although Nasdaq evaluates whether a

listed company is a public shell company based on a facts and circumstances determination, a Nasdaq-listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell company. Listed companies determined to be public shell companies by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria.

On August 9, 2024, Salarius reported in its Quarterly Report on Form 10-Q that for the three months ended June 30, 2024, its stockholders' equity was approximately $2.3 million. As further disclosed in that Quarterly Report on Form 10-Q, subsequent to June 30, 2024, Salarius sold 564,730 shares of its common stock for gross proceeds of approximately $1.5 million pursuant to that certain At the Market Offering Agreement, dated as of February 5, 2021, with Ladenburg Thalmann & Co. Inc. (the "ATM Financing Transaction"). On August 13, 2024, Salarius reported via Current Report on Form 8-K that Salarius regained compliance with the Stockholders' Equity Requirement after giving effect to the ATM Financing Transaction. Notwithstanding the foregoing, Nasdaq will continue to monitor Salarius' ongoing compliance with the Stockholders' Equity Requirement and, if at the time of the next periodic report Salarius does not evidence compliance, Salarius' common stock may be subject to delisting.

Salarius is actively monitoring the market value of its publicly held securities and its stockholders' equity and will consider any and all options available to it to maintain compliance. There can be no assurance, however, that Salarius will be able to maintain compliance and meet Nasdaq's continued listing requirements.

If Salarius' common stock is delisted from Nasdaq, whether because Nasdaq determines Salarius is a "public shell" or Salarius fails to maintain compliance with the continued listed requirements, or otherwise, Salarius' securities may qualify for trading over-the-counter ("OTC"), in the United States on a market colloquially referred to as the "Pink Sheets." Securities quoted on OTC are generally subject to lesser requirements than securities listed for trading on a U.S. national stock exchange, such as Nasdaq, including reduced corporate governance and public reporting standards. If Nasdaq should delist Salarius' common stock from trading, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of Salarius' common stock: the liquidity of the common stock; the market price of the common stock; the number of institutional and general investors that will consider investing in the common stock; the number of investors in general that will consider investing in the common stock; the number of market makers in the common stock; the availability of information concerning the trading prices and volume of the common stock; and the number of broker-dealers willing to execute trades in the common stock. In addition to the foregoing, there are certain consequences under the Securities Act of 1933, as amended (the "Securities Act"), of being a public shell company, including the unavailability of Rule 144 thereunder for the resale of restricted securities and the inability to utilize Form S-8 for the registration of employee benefit plan securities.

Salarius is substantially dependent on its remaining employees and consultants to facilitate the consummation of the Merger.

As of January 14, 2025, Salarius had only two full-time employees and one consultant acting as Salarius' Chief Executive Officer. Salarius' ability to successfully complete the Merger depends in large part on its ability to retain certain remaining personnel. Despite Salarius' efforts to retain these employees, one or more may terminate their employment or consulting arrangement with Salarius on short notice. The loss of the services of certain employees could potentially harm Salarius' ability to consummate the Merger, to run its day-to-day business operations, as well as to fulfill its reporting obligations as a public company.

The pendency of the Merger could have an adverse effect on the trading price of Salarius' common stock and its business, financial condition and prospects.

The pendency of the Merger could disrupt Salarius' business in many ways, including:

- the attention of its remaining management and employees may be directed toward the completion of the Merger and related matters and may be diverted from Salarius' day-to-day business operations; and
- third parties may seek to terminate or renegotiate their relationships with Salarius as a result of the Merger, whether pursuant to the terms of their existing agreements with Salarius or otherwise.

Should they occur, any of these matters could adversely affect the trading price of Salarius' common stock or harm its business, financial condition and prospects.

Salarius has never generated any revenue from product sales and may never generate revenue or be profitable.

Salarius has no products approved for commercialization and has never generated any revenue. Salarius' ability to generate revenue and achieve profitability depends on Salarius' ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of its product candidates. Salarius does not anticipate generating revenue from product sales for the foreseeable future. Salarius' ability to generate future revenue from product sales depends heavily on Salarius' success in many areas, including but not limited to:

- completing research and development of its product candidates;
- obtaining regulatory and marketing approvals for its product candidates;
- manufacturing product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible, meet regulatory requirements and supply needs in sufficient quantities to meet market demand for Salarius' product candidates, if approved;
- marketing, launching and commercializing product candidates for which Salarius obtains regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of Salarius' product candidates as treatment options;
- addressing any competing products;
- protecting and enforcing Salarius' intellectual property rights, including patents, trade secrets, and know-how;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which Salarius may enter;
- obtaining reimbursement or pricing for Salarius' product candidates that supports profitability; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that Salarius develops is approved for commercial sale, Salarius would need to incur significant costs associated with commercializing any approved product candidate. Portions of Salarius' current pipeline of product candidates have been in-licensed from third parties, which make the commercial sale of such in-licensed products potentially subject to additional royalty and milestone payments to such third parties. Salarius will also have to develop, contract for or acquire manufacturing capabilities to continue development and potential commercialization of Salarius' product candidates. Salarius will need to develop or procure its drug product in a commercially feasible manner in order to successfully commercialize any future approved product, if any. Additionally, if Salarius is not able to generate revenue from the sale of any approved products, Salarius may never become profitable.

Risks Related to the Development of Salarius' Product Candidates

The approach Salarius has taken to discover and develop novel oncology therapeutics using epigenetic enzymes to moderate transcription factors and thereby control abnormal protein expression is unproven and may never lead to marketable products.

The scientific discoveries that have formed the basis for Salarius' efforts to discover and develop Salarius' product candidates are relatively recent. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. The successful development of therapeutic products will require solving a number of issues. In addition, any product candidates that Salarius decides to develop further may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory and pre-

clinical trials, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways. For instance, Salarius' clinical and pre-clinical data to date is not validated and Salarius has no way of knowing if after validation Salarius' clinical trial data will be complete and consistent. If Salarius does not successfully develop and commercialize product candidates based upon this technological approach, Salarius may not become profitable and the value of Salarius' capital stock may further decline.

Further, Salarius' focus on epigenetic enzyme technology for developing product candidates as opposed to multiple, more proven technologies for drug development has increased the risk associated with Salarius' business. Salarius is not able to identify and successfully implement an alternative product development strategy due to Salarius' previous investments in current product candidates. In addition, work by other companies pursuing similar technologies may encounter setbacks and difficulties that regulators and investors may attribute to Salarius' product candidates, whether appropriate or not.

Clinical trials are costly, time consuming and inherently risky, and may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Clinical development is expensive, time consuming and involves significant risk. If Salarius decides to move forward with Salarius' clinical trials, Salarius cannot guarantee that they will be conducted as planned or completed on schedule, if at all. Salarius currently does not have the funds to advance Salarius' planned clinical trials. A failure of one or more of these clinical trials can occur at any stage of development.

Salarius' product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by Salarius' product candidates could cause Salarius, an IRB or ethics committee, or regulatory authorities to continue the clinical hold status, interrupt, delay, or terminate clinical trials or even if approved, result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities and potential product liability claims.

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier pre-clinical and clinical trials may not be predictive of future clinical trial results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical trials and early clinical trials of Salarius' product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Salarius' clinical trials to date have been conducted on a small number of patients in limited numbers of clinical sites for a limited number of indications. Moreover, clinical data are often susceptible to varying interpretations and analyses. Salarius cannot assure whether any clinical trials Salarius or The University of Texas MD Anderson Cancer Center ("MDACC") may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market Salarius' drug candidates.

Difficulty in enrolling patients is a common hurdle faced by early stage biotechnology companies and could, and often does, delay or prevent clinical trials of product candidates.

Identifying and qualifying patients to participate in clinical trials of Salarius' product candidates is essential to Salarius' existence. The timing of Salarius' clinical trials depends in part on the rate at which Salarius or investigators can recruit patients to participate in clinical trials of Salarius' product candidates, and Salarius and Salarius' investigators may experience delays in Salarius' clinical trials if Salarius or they encounter difficulties in enrollment.

Salarius may face potential product liability, and, if successful claims are brought against Salarius, Salarius may incur substantial liability and costs which could be greater than Salarius' insurance coverage or overall resources. If the use or misuse of Salarius' product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to Salarius' product candidates, Salarius' regulatory approvals, if any, could be revoked or otherwise negatively impacted and Salarius could be subject to costly and damaging product liability claims. If Salarius is unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, Salarius' insurance coverage, a material liability claim could adversely affect Salarius' financial condition.

The use or misuse of Salarius' product candidates in clinical trials and the sale of any products for which Salarius may obtain marketing approval exposes Salarius to the risk of potential product liability claims. Product liability claims might be brought against Salarius by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with Salarius' product candidates and approved products, if any. There is a risk that Salarius' product candidates may induce AEs.

Risks Related to Regulatory Approval of Salarius' Product Candidates and Other Legal Compliance Matters

Even if FDA grants breakthrough therapy designation for one or more of Salarius' product candidates, the designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that Salarius' product candidates will receive marketing approval, and FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for breakthrough therapy.

Salarius may seek a breakthrough therapy designation from the FDA for some of Salarius' product candidates that reach the regulatory review process. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA could also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if Salarius believes one of Salarius' product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation.

The receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of Salarius' product candidates qualify and are designated as breakthrough therapies, the FDA may later decide that the drugs or biological products no longer meet the conditions for designation and the designation may be rescinded.

Salarius has received fast track designation for one of Salarius' product candidates, but such designation may not actually lead to a faster development or regulatory review or approval process. Additionally, FDA may rescind the designation if it determines the product candidate no longer meets the qualifying criteria for fast track.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA fast track designation. Salarius received fast track designation for a product candidate. However, fast track designation does not ensure that Salarius will receive marketing approval or that approval will be granted within any particular time frame. Salarius may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from Salarius' clinical

development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

Salarius cannot guarantee how long it will take regulatory agencies to review Salarius' applications for product candidates, and Salarius may fail to obtain the necessary regulatory approvals to market Salarius' product candidates. If Salarius is not able to obtain required regulatory approvals, Salarius will not be able to commercialize Salarius' product candidates and Salarius' ability to generate revenue will be materially impaired.

Salarius' product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for Salarius' product candidates will prevent Salarius from commercializing them in those markets.

Salarius has not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither Salarius' current product candidates nor any product candidates that Salarius may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for Salarius to commence product sales.

Reliance on government funding for Salarius' programs may add uncertainty to Salarius' research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit Salarius' ability to take specified actions, increase the costs of commercialization and production of product candidates developed under those programs and subject Salarius to potential financial penalties, which could materially and adversely affect Salarius' business, financial condition and results of operations.

During the course of Salarius' development of Salarius' product candidates, Salarius has been funded in part through federal and state grants, including but not limited to the funding Salarius received from the Cancer Prevention and Research Institute of Texas ("CPRIT"). If Salarius does not comply with the terms of the grant, CPRIT may require Salarius to repay some or all of the disbursed grant.

Risks Related to Salarius' Intellectual Property

Salarius may not be successful in obtaining or maintaining necessary rights to Salarius' targets, product compounds and processes for Salarius' development pipeline through acquisitions and in-licenses.

Presently, Salarius has rights to the intellectual property, through licenses from third parties and under patents and patent applications that Salarius owns, to modulate only a subset of the known epigenetic enzyme targets. Because Salarius' programs may involve a range of targets, including targets that require the use of proprietary rights held by third parties, the growth of Salarius' business may depend in part on Salarius' ability to acquire, in-license or use these proprietary rights. In addition, Salarius' product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. Salarius may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that Salarius identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that Salarius may consider attractive. These established companies may have a competitive advantage over Salarius due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, Salarius has previously collaborated with academic institutions worldwide to accelerate Salarius' pre-clinical and clinical research or development under written agreements with these institutions. Typically, these institutions provide an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, Salarius may be unable to negotiate a license within the specified time frame or under terms that are acceptable to Salarius. If Salarius is unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking Salarius' ability to pursue its program.

In addition, companies that perceive Salarius to be a competitor may be unwilling to assign or license rights to Salarius. Salarius also may be unable to license or acquire third-party intellectual property rights on terms that would allow Salarius to make an appropriate return on Salarius' investment. If Salarius is unable to successfully obtain rights to third-party intellectual property rights, Salarius' business, financial condition and prospects for growth could suffer.

Salarius intends to rely on patent rights for Salarius' product candidates and any future product candidates. If Salarius is unable to obtain or maintain exclusivity from the combination of these approaches, Salarius may not be able to compete effectively in Salarius' markets.

Salarius relies or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to Salarius' technologies and product candidates. Salarius' success depends in large part on Salarius' and its licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to Salarius' proprietary technology and products.

Salarius has sought to protect Salarius' proprietary position by filing patent applications in the United States and abroad related to Salarius' product candidates that are important to Salarius' business. This process is expensive and time consuming, and Salarius may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that Salarius will fail to identify patentable aspects of Salarius' research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that Salarius owns or in-licenses may fail to result in issued patents with claims that cover Salarius' product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to Salarius' patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover Salarius' product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, Salarius' patents and patent applications may not adequately protect Salarius' intellectual property, provide exclusivity for Salarius' product candidates, or prevent others from designing around Salarius' claims. Any of these outcomes could impair Salarius' ability to prevent competition from third parties, which may have an adverse impact on Salarius' business.

Salarius, independently or together with Salarius' licensors, have filed several patent applications covering various aspects of Salarius' product candidates. Salarius cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to Salarius after patent issuance could deprive Salarius of rights necessary for the successful commercialization of any product candidates that Salarius may develop. Further, if Salarius encounters delays in regulatory approvals, the period of time during which Salarius could market a product candidate under patent protection could be reduced.

If Salarius cannot obtain and maintain effective protection of exclusivity from Salarius' regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for Salarius' product candidates, Salarius may not be able to compete effectively and Salarius' business and results of operations would be harmed.

Salarius may not have sufficient patent term protections for Salarius' product candidates to effectively protect Salarius' business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering Salarius' product candidates are obtained, once the patent life has expired for a product candidate, Salarius may be open to competition from generic medications. In addition, upon issuance in the United

States any patent term can be adjusted based on specified delays caused by the applicant(s) or the U.S. Patent and Trademark Office (the "USPTO").

Depending on the timing, duration, and conditions of FDA marketing approval of Salarius' product candidates, one or more of Salarius' United States patents may be eligible for patent term extension under the Hatch-Waxman Act. Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of Salarius' product candidates. Salarius will likely rely on patent term extensions, and Salarius cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. However, Salarius may not receive an extension if Salarius fails to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than Salarius requests. If Salarius is unable to obtain patent term extension or the term of any such extension is less than Salarius requests, the period during which Salarius can enforce Salarius' patent rights for that product may not extend beyond the current patent expiration dates and competitors may obtain approval to market competing products sooner. As a result, Salarius may not be able to maintain exclusivity for Salarius' product candidates for an extended period after regulatory approval, if any, which would negatively impact Salarius' business, financial condition, results of operations and prospects. If Salarius does not have sufficient patent terms or regulatory exclusivity to protect Salarius' product candidates, Salarius' business and results of operations will be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing Salarius' ability to protect Salarius' products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of Salarius' patent applications and the enforcement or defense of Salarius' issued patents

As is the case with other biotechnology companies, Salarius' success is heavily dependent on patents and the ability to enforce and protect these patients. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to Salarius' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken Salarius' ability to obtain new patents or to enforce Salarius' existing patents and patents that Salarius might obtain in the future. Some of Salarius' patent claims may be affected by the recent U.S. Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics. In Myriad, the Supreme Court held that unmodified isolated fragments of genomic sequences, such as the DNA constituting the BRCA1 and BRCA2 genes, are not eligible for patent protection because they constitute a product of nature. The exact boundaries of the Supreme Court's decision remain unclear as the Supreme Court did not address other types of nucleic acids.

If Salarius is unable to maintain effective proprietary rights for Salarius' product candidates or any future product candidates, Salarius may not be able to compete effectively in Salarius' proposed markets.

In addition to the protection afforded by patents, Salarius relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that Salarius elects not to patent, processes for which patents are difficult to enforce and any other elements of Salarius' product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. Salarius seek to protect Salarius' proprietary technology and processes, in part, by entering into confidentiality agreements with Salarius' employees, consultants, scientific advisors, and contractors. Salarius also seeks to preserve the integrity and confidentiality of Salarius' data and trade secrets by maintaining physical security of Salarius' premises and physical and electronic security of Salarius' information technology systems. While Salarius has confidence in these individuals, organizations and systems, agreements or security measures may be breached, and Salarius may not have adequate remedies for any breach. In addition, Salarius' trade secrets may otherwise become known or be independently discovered by competitors.

Third-party claims of intellectual property infringement may prevent or delay Salarius' development and commercialization efforts.

Salarius' commercial success depends in part on Salarius' ability to develop, manufacture, market and sell Salarius' product candidates and use Salarius' proprietary technology without infringing the patent rights of third parties.

Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the area of epigenetic enzyme inhibitors and related technologies. Salarius is aware of U.S. and foreign patents and pending patent applications owned by third parties that cover therapeutic uses of epigenetic inhibitors. Salarius is currently monitoring these patents and patent applications. Salarius may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, Salarius may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications. If any patents or patent applications cover Salarius' product candidates or technologies, Salarius may not be free to manufacture or market Salarius' product candidates, as planned, absent such a license, which may not be available to Salarius on commercially reasonable terms, or at all.

Salarius may not be successful in meeting Salarius' obligations under Salarius' existing license agreements necessary to maintain Salarius' product candidate licenses in effect. In addition, if required in order to commercialize Salarius' product candidates, Salarius may be unsuccessful in obtaining or maintaining necessary rights to Salarius' product candidates through acquisitions and in-licenses.

Salarius currently has rights to the intellectual property, through licenses from third parties and under patents that Salarius does not own, to develop and commercialize Salarius' product candidates. Because Salarius' programs may require the use of proprietary rights held by third parties, the growth of Salarius' business will likely depend in part on Salarius' ability to maintain in effect these proprietary rights. Any termination of license agreements with third parties with respect to Salarius' product candidates would be expected to negatively impact Salarius' business prospects.

Salarius may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that Salarius identifies as necessary for Salarius' product candidates.

If Salarius fails to comply with obligations in the agreements under which Salarius licenses intellectual property and other rights from third parties or otherwise experience disruptions to Salarius' business relationships with Salarius' licensors, Salarius could lose license rights that are important to Salarius' business.

Salarius is a party to intellectual property licenses and supply agreements that are important to Salarius' business and may enter into additional license agreements in the future. Salarius' existing agreements impose, and Salarius expects that future license agreements will impose on Salarius, various diligence, milestone payment, royalty, purchasing, and other obligations. If Salarius fails to comply with Salarius' obligations under these agreements, or Salarius is subject to a bankruptcy, Salarius' agreements may be subject to termination by the licensor, in which event Salarius would not be able to develop, manufacture, or market products covered by the license or subject to supply commitments.

Salarius may be involved in lawsuits to protect or enforce Salarius' patents or the patents of Salarius' licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe Salarius' patents or the patents of Salarius' licensors. If Salarius or one of Salarius' licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of Salarius' product candidates, the defendant could counterclaim that the patent covering Salarius' product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, clarity or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with

prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Salarius may not be able to protect Salarius' intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and Salarius' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use Salarius' technologies in jurisdictions where Salarius has not obtained patent protection to develop Salarius' own products and may also export infringing products to territories where Salarius has patent protection, but enforcement is not as strong as that in the United States. These products may compete with Salarius' products and Salarius' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Risks Related to Salarius' Reliance on Third Parties

Salarius relies on or will rely on third parties to conduct Salarius' clinical trials. If these third parties do not successfully perform and comply with regulatory requirements, Salarius may not be able to successfully complete clinical development, obtain regulatory approval or eventually commercialize Salarius' product candidates and Salarius' business could be substantially harmed.

Salarius has relied upon and plan to continue to rely upon third-parties such as contract research organizations ("CROs"), hospitals and clinical investigators to study Salarius' product candidates in clinical trials. For example, Salarius has collaborated with The University of Texas MD Anderson Cancer Center ("MDACC") to study SP-2577 in combination with azacitidine for the treatment of patients with myelodysplastic syndromes or chronic myelomonocytic leukemia . Salarius relies on these parties for the execution of clinical trials and Salarius only manages and controls some aspects of their activities. With respect to the MDACC sponsored investigator initiated trial, Salarius supplies seclidemstat in quantities required to conduct the clinical trial, but does not have any control over their development activities or the timing thereof. Salarius remains responsible for ensuring that each of Salarius' trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and Salarius' reliance on these third parties does not relieve Salarius of its regulatory responsibilities. The trial remains on partial clinical hold following a serious and unexpected grade 4 adverse event while MDACC works with the FDA to resolve the partial clinical hold.

Salarius expects to rely on third parties to manufacture Salarius' clinical product supplies, and Salarius intends to rely on third parties to produce and process Salarius' product candidates, if approved, and Salarius' commercialization of any of Salarius' product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of government regulators, fail to comply with applicable regulations, fail to provide Salarius with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

Salarius does not currently have nor does Salarius currently plan to develop the infrastructure or capability internally to manufacture Salarius' clinical supplies for use in the conduct of Salarius' clinical trials, and Salarius lacks the resources and the capability to manufacture any of Salarius' product candidates on a clinical or commercial scale. Salarius currently relies on outside vendors to manufacture the clinical supplies of Salarius' product candidates. Salarius plans to continue relying on third parties to manufacture Salarius' product candidates on a commercial scale, if approved.

Salarius does not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of Salarius' product candidates and Salarius' current costs to manufacture Salarius' drug products is not commercially feasible, and the actual cost to manufacture Salarius' product candidates could materially and adversely affect the commercial viability of Salarius' product candidates. As a result, Salarius may never be able to develop a commercially viable product.

Risks Related to Decoy

Risks Related to Decoy's Business

Decoy's financial condition raises substantial doubt regarding its ability to continue as a going concern.

Decoy's consolidated financial statements have been prepared assuming that Decoy will continue to operate as a going concern, which contemplates the realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Based on Decoy's current operations and operating plans, however, Decoy believes that its existing cash and cash equivalents will not be sufficient to fund Decoy's operating expenses and capital expenditure requirements for the next 12 months. Included in Decoy's anticipated future capital needs will be capital for advancing Decoy's research and development activities including Decoy's goal to begin a Phase 1 clinical trial for DCOY-101 potentially in the first half of 2026. As a result, Decoy has determined that there is substantial doubt regarding Decoy's ability to continue as a going concern, and Decoy's independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2023, an explanatory paragraph about such substantial doubt regarding Decoy's ability to continue as a going concern.

The substantial doubt regarding Decoy's ability to continue as a going concern may adversely affect Decoy's stock price and its ability to raise capital necessary to execute Decoy's current operating plans. If Decoy is unable to obtain additional capital, it may not be able to continue its operations on the scope or scale as currently conducted, and Decoy could be forced to cease operations, in which case you could lose all or most of your investment.

Decoy has never generated revenue from product sales and all of Decoy's product candidates are currently in the preclinical stage, and Decoy may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.

Decoy is a preclinical biopharmaceutical discovery and development company. Decoy plans to bring certain product candidates into the early stages of clinical development beginning in the first half of 2026, however its ability to do so will depend on factors beyond Decoy's control, including its ability to raise capital and to effectively navigate the regulatory requirements, particularly those imposed by the FDA which are described elsewhere in these Risk Factors and in this prospectus. Because of the need to proceed to and complete clinical trials, establish safety and efficacy and obtain regulatory approval, which is an expensive and time-consuming process, Decoy does not anticipate generating revenue from product sales for at least several years and will continue to sustain considerable losses during that time. Decoy may develop a partnership that could generate income sooner, but there is no guarantee that will be achievable.

Because Decoy has yet to generate revenue from product sales on which to evaluate its potential for future success and to determine if Decoy will be able to execute its business plan, it is difficult to evaluate Decoys' prospects and the likelihood of success or failure of its business.

Decoy's ability to generate revenue from product sales and achieve profitability depends on its ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for and commercialize pharmaceutical product candidates. Decoy has no pharmaceutical product candidates that have proceed to clinical trials or generated any commercial revenue, does not expect to generate revenues from the commercial sale of pharmaceutical products for foreseeable future, and may never generate revenues from the sale of pharmaceutical products. Decoy's ability to generate revenue and achieve profitability will depend on, among other things, the following:

- identifying and validating new therapeutic strategies;
- entering into and maintaining collaborations and relationships with large pharmaceutical or biotechnology companies;
- completing its research and preclinical development of pharmaceutical product candidates;
- initiating and completing clinical trials for pharmaceutical product candidates;

- seeking and obtaining regulatory marketing approvals for pharmaceutical product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing pharmaceutical product candidates for which Decoy obtains regulatory marketing approval with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting, enforcing, defending and expanding its intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, Decoy cannot predict the timing or amount of increased expenses and when it will be able to achieve or maintain profitability, if ever. Decoy's expenses could increase beyond expectations if it is required by regulatory agencies to perform additional unanticipated studies and trials.

Even if one or more pharmaceutical product candidates Decoy independently develops is approved for commercial sale, Decoy anticipates incurring significant costs associated with commercializing any approved pharmaceutical product candidate. Moreover, even if Decoy can generate revenues from the sale of any approved pharmaceutical products, Decoy may not become profitable and may need to obtain additional funding to continue operations.

Because early-stage drug development requires major capital investment, as Decoy continues to incur operating losses, it will need to raise additional capital or form strategic partnerships to support its research and development activities in the future.

Decoy is still in the early stages of development of its product candidates, and has no products approved for commercial sale or presently in clinical trials. Decoy's ability to proceed to and conduct clinical trials in a cost-effective manner and within the desired timeframes remains subject to uncertainties including the potential for supply chain shortages and difficulties in obtaining adequate participant enrollments which are common challenges faced in conducting clinical trials. Further, developing pharmaceutical products, including conducting preclinical studies and clinical trials, is capital-intensive. As a rule, research and development expenses increase substantially as product candidates are advanced toward clinical programs. If Decoy is able to advance its products to and through clinical trials, it may need to raise additional capital to support its operations and/or form partnerships, in addition to its existing collaborative alliances, which may give substantial rights to a partner. Such funding or partnerships may not be available to Decoy on acceptable terms, or at all. Moreover, any future financing may be very dilutive to Decoy's existing stockholders.

As Decoy moves lead compounds through toxicology and other preclinical studies, also referred to as nonclinical studies, it has and will be required to file an IND or its equivalent in foreign countries, and as it conducts clinical development of product candidates, it may have adverse results that may cause Decoy to consume additional capital. Decoy's partners may not elect to pursue the development and commercialization of Decoy's product candidates subject to Decoy's respective agreements with them. These events may increase Decoy's development costs more than it expects. Decoy may need to raise additional capital or otherwise obtain funding through strategic alliances if it initiates clinical trials for new product candidates other than programs currently partnered. Decoy will require additional capital to obtain regulatory approval for, and to commercialize, product candidates.

In securing additional financing, such additional fundraising efforts may divert Decoy's management's attention from its day-to-day activities, which may adversely affect its ability to develop and commercialize product candidates. Decoy cannot guarantee that future financing will be available in sufficient amounts or on terms

acceptable to Decoy, if at all. If Decoy cannot raise additional capital when required or on acceptable terms, it may be required to:

- accept terms that restrict its ability to issue securities, incur indebtedness, or otherwise raise capital in the future, or restrict its ability to pay dividends or engage in acquisitions;
- significantly delay, scale back or discontinue the development or commercialization of any product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, its rights to technologies or any product candidates Decoy otherwise would seek to develop or commercialize itself.

If Decoy is unable to raise additional capital in sufficient amounts or on terms acceptable to Decoy, it will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on its business, operating results and prospects or may render Decoy unable to continue operations.

Risks Related to the Discovery, Development and Commercialization of Product Candidates by Decoy

If any strategic alliances on which Decoy depends are unsuccessful or are terminated, Decoy may be unable to develop or commercialize certain product candidates and it may be unable to generate revenues from its development programs.

Decoy will likely need to use third-party alliance partners for financial, scientific, manufacturing, marketing and sales resources for the development and commercialization of its product candidates. Decoy also presently relies on a number of third party vendors for a variety of operational functions, including the provision of its technology infrastructure and other elements of its product candidate development programs as well as critical data storage and processing functions. These strategic alliances, if Decoy is able to enter into, foster and maintain them, will likely constrain its control over development and commercialization of its product candidates, especially once a candidate has reached the stage of clinical development. Decoy's ability to recognize revenues from successful strategic alliances may be impaired by several factors including a partner shifting its priorities and resources away from Decoy, failing to perform under required standards or contractual terms, terminating the relationship with Decoy, entering into a dispute or litigation with Decoy or third parties or ceasing operations.

For example, Decoy relies and expects to continue to rely on third parties to conduct some aspects of its preclinical testing and on third-party CROs to conduct clinical trials. This reliance can materially delay Decoy's research and developments efforts, and increase the costs of undertaking them. Further, any disputes that may arise from Decoy's arrangements with CROs or contract manufacturing organizations ("CMOs") may result in additional unexpected expenses and force Decoy's management to allocate their limited time to seeking a resolution to the problem, which could materially adversely affect Decoy's operations.

Additionally, Decoy's reliance on third-party manufacturers to develop products and its anticipated reliance on third-party manufacturers to produce products it may develop in the future entail risks to which Decoy would not be subject if it supplied the materials needed to develop and manufacture its product candidates itself, including supply chain shortages, the inability to meet any product specifications and quality requirements consistently, a delay or inability to procure or expand sufficient manufacturing capacity, and a failure to comply with current "cGMP" and similar foreign standards. These events could lead to clinical study delays or failure to obtain regulatory approval or impact Decoy's ability to successfully commercialize future products. Some of these events could be the basis for regulatory actions, including injunction, recall, seizure or total or partial suspension of production.

Termination of or other adverse development with respect to a strategic alliance may require Decoy to seek out and establish alternative strategic alliances with third-party partners. This may not be possible, including due to restrictions under the terms of Decoy's collaborations, or Decoy may not be able to do so on terms acceptable to Decoy. If Decoy fails to establish alternative strategic alliances with third-party partners on terms acceptable to

Decoy, or at all, it may be required to limit the size or scope of one or more of its programs or decrease its expenditures and seek additional funding by other means. Such events would likely have a material adverse effect on Decoy's results of operations and financial condition.

Since Decoy expects to rely on third parties to conduct, supervise and monitor any future clinical trials, if those third parties fail to perform in a satisfactory manner and one that meets applicable regulatory, scientific and safety requirements, it may materially harm Decoy's business.

If and when Decoy is able to proceed to clinical trial for a product candidate, it will rely on CROs and clinical trial sites to ensure the proper and timely conduct of its clinical trials. Decoy anticipates that Decoy or its partners will have limited influence over their actual performance. Nevertheless, Decoy or its partners will be responsible for ensuring that each of its clinical trials is conducted in accordance with its protocol, and that all legal, regulatory and scientific standards are met. Decoy's reliance on the CROs does not relieve Decoy of its regulatory responsibilities.

Decoy, its partners and its CROs must comply with current Good Clinical Practices ("cGCPs"), as defined by the FDA and the International Conference on Harmonization, for conducting, recording and reporting the results of IND-enabling preclinical studies and clinical trials, to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators, and clinical trial sites. If Decoy or its CROs fail to comply with cGCPs, the clinical data generated in Decoy's clinical trials may be deemed unreliable and the FDA or other regulators may require Decoy to perform additional clinical trials before approving any marketing applications. Decoy's clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a product candidate. If Decoy's CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, fail to recruit properly qualified patients or fail to properly record or maintain patient data, Decoy may be required to repeat such clinical trials, which would delay the regulatory approval process.

Decoy's contracted CROs will not be Decoy's employees, and Decoy cannot control whether they devote sufficient time and resources to Decoy's clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including Decoy's competitors, for whom they may also be conducting clinical trials, or other drug development activities that could harm Decoy's competitive position. If Decoy's CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to failing to adhere to Decoy's clinical protocols or regulatory requirements, or for any other reasons, Decoy's clinical trials may be extended, delayed or terminated, and Decoy may not obtain regulatory approval for, or successfully commercialize its product candidates. Decoy's financial results and the commercial prospects for such products and any product candidates it develops would be harmed, its costs could increase, and its ability to generate revenues could be delayed.

Decoy also expects to rely on other third parties to store and distribute drug products for any clinical trials it may conduct. Any performance failure by Decoy's distributors could delay clinical development or marketing approval of its product candidates or commercialization of its products, if approved, producing additional losses and depriving Decoy of potential product revenue.

Because the approach Decoy is taking to discover and develop drugs is novel, it may never lead to marketable products.

Decoy is concentrating its therapeutic product research and development efforts on using its proprietary technology, and Decoy's future success depends on the continued successful development of this technology and the products derived from it. Decoy has never commercialized any products. The scientific discoveries that form the basis for Decoy's efforts to discover and develop drug product candidates are relatively new and unproven. The scientific evidence to support the feasibility of developing product candidates based on Decoy's approach is limited. If Decoy does not successfully develop and commercialize drug product candidates based upon its technological approach, it may not become profitable and the value of its stock may decline.

Further, Decoy's approach to drug development involves the use of artificial intelligence ("AI") and computing software to identify potential molecules for further research and development processes. The use of AI is relatively novel, and the underlying technology continues to experience substantial changes with the passage of time and as

considerable resources continue to be deployed in the market. Decoy is therefore subject to unique risks and uncertainties based on its reliance on and involvement in AI for its operations, including the risk of regulatory developments that may adversely affect or hinder its ability to use this technology or expose Decoy to potential liability arising from such use, the risk that competitors develop or deploy similar or superior systems in their operations that give them an advantage over Decoy, and the risk that the third parties on which Decoy relies for its technology and infrastructure fail to perform as needed or fail to protect its rights, technology, data and interests. Further, Decoy relies on a relatively small number of third parties for services and infrastructure related to its technology, and any loss or diminishment of any of those relationships could significantly harm its business, and Decoy may be unable to find a suitable replacement for those functions in a reasonable amount of time, on favorable terms or at all.

If Decoy does not succeed in its efforts to identify or discover additional potential product candidates, your investment may be lost.

The success of Decoy's business depends primarily upon its ability to identify, develop and commercialize drug products, an extremely risky business. Decoy's research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for several reasons, including:

- Decoy's research methodology or that of its partners may be unsuccessful in identifying potential product candidates;
- potential product candidates may have harmful side effects or may have other characteristics that make the products unmarketable or unlikely to receive marketing approval; and
- Decoy or its partners may change their development profiles for potential product candidates or abandon a therapeutic area.

Such events may force Decoy to abandon its development efforts for a program or programs, which would have a material adverse effect on its business and could cause Decoy to cease operations. Research programs to identify new product candidates require substantial technical, financial, and human resources. Decoy may focus its efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Because Decoy's future commercial success depends on gaining regulatory approval for its products, Decoy cannot generate revenue without obtaining approvals.

Decoy's long-term success and generation of revenue will depend upon the successful development of new products from its research and development activities, including those licensed or acquired from third parties. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, the FDA indicates that approximately 70% of drugs proceed past Phase 1 studies, 33% proceed past Phase 2, and just 25%-30% proceed past Phase 3 to Phase 4 which is the final phase in the FDA review and approval process for marketing therapeutic product candidates. The process for obtaining regulatory approval to market product candidates is expensive, usually takes many years, and can vary substantially based on the type, complexity, and novelty of the product candidates involved. Decoy's ability to generate revenue would be adversely affected if Decoy is delayed or unable to successfully develop its products.

Decoy may also pursue and deploy substantial resources and time towards seeking accelerated or limited approval processes that it may be deemed to not qualify for or may otherwise not be granted, in which case those efforts and resources will have been lost, and a delay or inability to obtain the approval for the applicable product candidate may result.

Decoy cannot guarantee that any marketing application for its product candidates will be approved. If Decoy does not obtain regulatory approval of its products or Decoy is significantly delayed or limited in doing so, Decoy cannot generate revenue, and it may need to significantly curtail operations.

If Decoy is unable to successfully complete preclinical testing and clinical trials of its product candidates or experience significant delays in doing so, its business will be materially harmed.

Decoy has invested and intends to continue to invest a significant portion of its efforts and financial resources in the identification and preclinical development of product candidates that target select diseases, including viral diseases and colon cancer. Decoy's ability to generate product revenues, which it does not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of its product candidates.

The commercial success of Decoy's product candidates will depend on several factors, including:

- successful completion of preclinical studies and clinical trials;
- receipt of marketing and pricing approvals from regulatory authorities;
- obtaining and maintaining patent and trade secret protection for product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing Decoy's own manufacturing capability; and
- commercializing Decoy's products, if and when approved, whether alone or in collaboration with others.

If Decoy does not achieve one or more of these factors in a timely manner or at all, it could experience significant delays or an inability to successfully complete development of, or to successfully commercialize, its product candidates, which would materially harm its business. Pharmaceutical products that do overcome the low probability of success of drug development and achieve commercialization often do not recoup their cost of capital. If Decoy is unable to design and develop each drug to meet a commercial need far in the future, the approved drug may become a commercial failure and Decoy's investment in those development and commercialization efforts will have been commercially unsuccessful.

Decoy may be unable to demonstrate safety and efficacy of its product candidates to the satisfaction of regulatory authorities or it may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, Decoy or its partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not predict final results. Moreover, preclinical, and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Events that may cause a delay or unsuccessful completion of clinical development include, among other things:

- delays in agreeing with the FDA or other regulatory authorities on final clinical trial design;
- imposition of a clinical hold following an inspection of a clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in agreeing on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;
- delays in recruiting suitable patients to participate in a trial;

- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- negative or inconclusive results of clinical trials of product candidates;
- time and expenses required to add new clinical sites; or
- delays by contract manufacturers in producing and delivering sufficient supply of clinical trial materials.

If Decoy or its partners must conduct additional clinical trials or other testing of any product candidates beyond those that are contemplated, or are unable to successfully complete clinical trials or other testing of any of its product candidates, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, Decoy or its partners may be subject to delays in or restriction from obtaining marketing approval for its product candidates, negative labeling and marketing requirements, additional post-marketing testing requirements, or actions by regulatory agencies to remove the product from a target market after obtaining marketing approval.

Decoy's product development costs will also increase if Decoy experiences delays in testing or in obtaining marketing approvals. Decoy does not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could shorten any periods during which Decoy may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before Decoy does, which would impair its ability to successfully commercialize its product candidates and may harm its business and results of operations. Any inability to successfully complete preclinical and clinical development, whether independently or with Decoy's partners, could cause additional costs to Decoy or impair its ability to generate revenues from its product candidates, including product sales, milestone payments, profit sharing or royalties.

Decoy's product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events ("AEs") or serious adverse events ("SAEs"), that may be observed during clinical trials of Decoy's product candidates could cause Decoy, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt such trials and could cause denial of regulatory approval. If AEs or SAEs are observed in any clinical trials of Decoy's product candidates, including those Decoy's partners may develop under alliance agreements, Decoy or its partners' ability to obtain regulatory approval for product candidates may be negatively impacted.

Serious or unexpected side effects caused by an approved product could result in significant negative consequences, including the following:

- regulatory authorities may withdraw prior approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy ("REMS") which may restrict the manner in which the product can be distributed or administered;
- Decoy may be required to add labeling statements, such as warnings or contraindications;
- Decoy may be required to change the way the product is administered or conduct additional clinical trials;
- Decoy may decide or be forced to temporarily or permanently remove the affected product from one or more target markets or from the marketplace in general;
- Decoy could be sued and held liable for harm caused to patients; and

- Decoy's reputation may suffer.

These events could prevent Decoy or its partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing Decoy's products and impair its ability to generate revenues from the commercialization of these products either by Decoy or by its partners.

Following regulatory approval for a product candidate, Decoy will still face extensive regulatory requirements and the approved product may face future development and regulatory difficulties.

Even if Decoy obtains regulatory approval in the United States or elsewhere, the applicable regulators may still impose significant restrictions on the indicated uses or marketing of its product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The following discussion is based on United States law. Similar types of regulatory provision apply outside of the United States.

The holder of an approved new drug application ("NDA") must monitor and report AEs and SAEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and other applicable federal and state laws and are subject to FDA review.

Drug product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs, and adherence to commitments made in the NDA. If Decoy or a regulatory agency discovers previously unknown problems with a product such as AEs or SAEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If Decoy or its partners fail to comply with regulatory requirements following approval of Decoy's product candidates, a regulatory agency may:

- issue a warning letter asserting Decoy is in violation of the law;
- impose a REMS, or other restrictions on the manufacturing, marketing or use of the product;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any clinical trials Decoy may commence in the future;
- refuse to approve a pending NDA or supplements to an NDA submitted by Decoy;
- seize product; or
- refuse to allow Decoy to enter into supply contracts, including government contracts.

Decoy's defense of any government investigation of alleged violations of law, or any lawsuit alleging such violations, could require decoy to expend significant time and resources and could generate negative publicity. Further, the FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of Decoy's product candidates or increase the cost of compliance. The occurrence of any event or penalty described above may prevent or inhibit Decoy's ability to commercialize its products and generate revenues.

Decoy may not succeed in obtaining or maintaining necessary rights to drug compounds and processes for its development pipeline through acquisitions and in-licenses.

Decoy may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties it identifies. The licensing and acquisition of third-party intellectual

property rights is a competitive area, and more established companies are also pursuing strategies to license or acquire third-party intellectual property rights Decoy may consider attractive. These established companies may have a competitive advantage over Decoy due to their size, cash resources and greater clinical development and commercialization capabilities.

Companies that perceive Decoy to be a competitor may be unwilling to assign or license rights to Decoy. Decoy also may be unable to license or acquire third-party intellectual property rights on terms that would allow Decoy to make an appropriate return on its investment. If Decoy is unable to successfully obtain rights to required third-party intellectual property rights, its business, financial condition, and prospects for growth could suffer.

Decoy's product development programs are in the preclinical stage and Decoy faces significant competition from major companies who have developed or are developing vaccines or treatments for the diseases Decoy is targeting, and if Decoy fails to gain market share because its competitors develop and successfully commercialize vaccines or treatments, its business and future prospects could be materially and adversely affected.

Decoy may be unable to develop or proceed with the onerous regulatory requirements for clinical programs necessary to produce an effective therapy in a timely manner or at all. Additionally, Decoy is committing substantial financial and other resources to its drug development programs, which may occur at the expense of other potential drug candidate programs Decoy could have otherwise and thereby negatively impact such other programs. Even if Decoy does obtain FDA authorization for a therapeutic product, the FDA may subsequently rescind or limit such authorization as more information about the product, including its efficacy and side effects, becomes available. Further, a virus Decoy targets, such as COVID-19 which is highly mutative and a number of variants have already arisen, will render any product candidates it develops subject to the risk that a mutation will occur that produces a strain or strains of the virus to which such treatment has a diminished effect or is ineffective. If Decoy does develop a treatment that is effective against a current version of a disease, a later variant may arise that reduces or eliminates the product's efficacy before Decoy is able to commercialize it. Further, if this occurs, one or more competitors' products may be more effective against new variants than Decoy's, resulting in a diminished market for Decoy's products. If Decoy is unable to timely advance its programs, or if Decoy fails to gain or maintain a market share as a result of its competitors developing and successfully commercializing effective vaccines and therapies more quickly than Decoy does, its business and future prospects could be materially and adversely affected.

Further, because third parties may be developing competitive products without Decoy's knowledge, Decoy may later learn that competitive products are superior to its product candidates which may force Decoy to terminate its research efforts of one or more product candidates. If in the future, Decoy learns of the existence of one or more competitive products, Decoy may be required to cease its development efforts for a product candidate. Any of these events may occur after Decoy has spent substantial sums in connection with the clinical research of one or more product candidates.

Decoy has limited experience in conducting and managing the preclinical development activities and clinical trials necessary to obtain approvals for marketing its product candidates, including approval by the FDA.

Decoy's efforts to develop its product candidates are limited to a small number of product candidates aimed at treating a small number of viral diseases and colon cancer. To date, Decoy has not advanced any product candidates to clinical trials, and it may be unable to progress its product candidates through the preclinical stage and into clinical trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will succeed, and favorable initial results from a clinical trial do not determine outcomes in subsequent clinical trials. The indications of use for which Decoy is pursuing development may have clinical effectiveness endpoints not previously reviewed or validated by the FDA or foreign regulatory authorities, which may complicate or delay its effort to obtain marketing approval. Decoy cannot guarantee that it will be able to proceed to clinical trials or that any future clinical trials will succeed. In fact, most compounds fail in clinical trials, even at companies far larger and more experienced than Decoy. If any preclinical or clinical trials yield adverse results, it could delay the development of the product candidate, force Decoy to cease pursuing the product candidate, or render it impossible or impracticable to proceed towards commercialization.

Decoy has not obtained marketing approval or commercialized any of its product candidates. Decoy may not successfully design or implement clinical trials required for marketing approval to market its product candidates. If Decoy is unsuccessful in conducting and managing its preclinical development activities or clinical trials or obtaining marketing approvals, it might not be able to commercialize its product candidates, or might be significantly delayed in doing so, which will materially harm its business.

Risks Related to Decoy's Operations and Industry

If Decoy cannot obtain or protect intellectual property rights related to its future products and product candidates, it may not be able to compete effectively in its markets.

Decoy relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to its future products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications Decoy owns or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to Decoy's patents and patent applications has been found; such prior art can invalidate a patent or prevent issuance of a patent based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may cause such patents to be narrowed or invalidated. Even if unchallenged, Decoy's patents and patent applications may not adequately protect Decoy's intellectual property or prevent others from designing around Decoy's claims.

If the patent applications Decoy holds or has in-licensed regarding its programs or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with Decoy to develop product candidates, and threaten its ability to commercialize products. Patents may not issue and issued patents may be found invalid and unenforceable or challenged by third parties. Since patent applications in the United States and most other countries are confidential for a period after filing, and some remain so until issued, Decoy cannot be certain that it was the first to invent a patent application related to a product candidate. In certain situations, if Decoy and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding can be initiated to determine which applicant is entitled to the patent on that subject matter. Patents have a limited lifespan. In the United States, the natural expiration of a patent is 20 years after it is filed, although various extensions may be available. The life of a patent, and the protection it affords, is limited. When the patent life has expired for a product, Decoy will become vulnerable to competition from generic medications attempting to replicate that product. Further, if Decoy encounters delays in regulatory approvals, the time during which decoy will be able to market and commercialize a product candidate under patent protection could be reduced.

In addition to patent protection, Decoy relies on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of its drug discovery and development processes that involve proprietary know-how, information or technology not covered by patents. Each of Decoy's employees agrees to assign their inventions to Decoy through an employee inventions agreement. In addition, as a general practice, Decoy's employees, consultants, advisors and any third parties who have access to Decoy's proprietary know-how, information or technology enter into confidentiality agreements. Nonetheless, Decoy's trade secrets and other confidential proprietary information may be disclosed and competitors may otherwise gain access to Decoy's trade secrets or independently develop substantially equivalent information and techniques.

The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. Decoy may encounter significant problems in protecting and defending its intellectual property both in the United States and abroad. Further, governments may in the future alter intellectual property rights in a manner adverse to Decoy or to its third-party collaborators, including actions taken at the international level.

If Decoy is unable to prevent material disclosure of the non-patented intellectual property related to its technologies to third parties, and there is no guarantee Decoy will have any such enforceable trade secret protection,

Decoy may not be able to establish or maintain a competitive advantage in its market, which could materially adversely affect its business, results of operations and financial condition.

If third-party intellectual property infringement claims are asserted against Decoy, it may prevent or delay Decoy's development and commercialization efforts and have a material adverse effect on its business and future prospects.

Decoy's commercial success depends in part on Decoy avoiding infringement on the patents and proprietary rights of third parties. There is substantial litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexaminations and other post-grant proceedings before the U.S. Patent and Trademark Office, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which Decoy and its partners are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Decoy's product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that Decoy is employing their proprietary technology or rights without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Decoy's product candidates. Because patent applications can take many years to issue, there may be patent applications currently pending that may later result in patents that Decoy's product candidates may infringe upon. Third parties may obtain patents in the future and claim that use of Decoy's technologies infringes on these patents. If any third-party patents were to be held by a court of competent jurisdiction to cover the manufacturing process of any of Decoy's product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block Decoy's ability to commercialize such product candidate unless Decoy obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were to be held by a court of competent jurisdiction to cover aspects of Decoy's formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block Decoy's ability to develop and commercialize the applicable product candidate unless Decoy obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making intellectual property claims against Decoy may obtain injunctive or other equitable relief, which could block its ability to further develop and commercialize one or more of its product candidates. Defense of these claims, regardless of their merit, involves substantial litigation expense and diversion of Decoy's management's attention from its business. If a claim of infringement against Decoy succeeds, Decoy may have to pay substantial damages, possibly including treble damages and attorneys' fees for willful infringement, pay royalties, redesign its infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Because of the costs involved in defending patent litigation, Decoy may in the future lack the capital to defend its intellectual property rights.

Decoy may in the future be involved in lawsuits to protect or enforce its patents or the patents of its licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe on Decoy's patents or the patents of its licensors. To counter such infringement or unauthorized use, Decoy may be required to file infringement claims, or it may be required to defend the validity or enforceability of such patents, which can be expensive and time-consuming. In an infringement proceeding, a court may decide that either one or more of Decoy's patents or its licensors' patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue because Decoy's patents do not cover that technology. An adverse result in any litigation or defense proceedings could put one or more of Decoy's patents at risk of being invalidated or interpreted narrowly and could put its patent applications at risk of not being issued.

Interference proceedings provoked by third parties or brought by Decoy may be necessary to determine the priority of inventions regarding Decoy's patents or patent applications or those of Decoy's partners or licensors. An

unfavorable outcome could require Decoy to cease using the related technology or to license rights to it from the prevailing party. Decoy's business could be harmed if the prevailing party does not offer Decoy a license on commercially reasonable terms. Decoy's defense or pursuit of litigation or interference proceedings may fail and, even if successful, may cause Decoy to incur substantial costs and distract the attention of its management and other employees. Decoy may not be able to prevent, alone or with its licensors, misappropriation of its intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of Decoy's confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of Decoy's common stock.

Decoy may need to obtain additional licenses to intellectual property rights from third parties.

Decoy may need to obtain additional licenses from third parties to advance its research or allow commercialization of its product candidates. Decoy may fail to obtain these licenses at a reasonable cost or on reasonable terms, if at all. In that event, Decoy would be unable to further develop and commercialize one or more of its product candidates, which could harm its business significantly. Decoy cannot provide any assurances that third-party patents do not exist that might be enforced against its products, resulting in either an injunction prohibiting its sales, or, with respect to its sales and other activities, an obligation on its part to pay royalties and/or other forms of compensation to third parties.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than Decoy does, may also be pursuing strategies to license or acquire third-party intellectual property rights that Decoy may consider necessary or attractive in order to develop and commercialize its product candidates. More established companies may have a competitive advantage over Decoy due to their larger size and cash resources or greater clinical development and commercialization capabilities. Decoy may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding product candidates that it may seek to acquire, in which case its business could be harmed.

Decoy may be subject to claims that its employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

Decoy employs individuals previously employed at other biotechnology or pharmaceutical companies. Decoy may be subject to claims asserting that Decoy or its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of Decoy's employees' former employers or other third parties. Decoy may also be subject to claims that former employers or other third parties have an ownership interest in Decoy's patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if Decoy succeeds, litigation could cause substantial cost and be a distraction to its management and other employees.

Because Decoy faces significant competition from other biotechnology and pharmaceutical companies, its operating results will suffer if it fails to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. Decoy has competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Decoy's competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may cause even more resources being concentrated in Decoy's competitors. Additionally, smaller or early-stage companies of which Decoy may not be aware could also prove to be material competitors, particularly through collaborative arrangements with larger, more well-established companies or by competing with Decoy for limited resources and strategic alliances with Decoy's current or

prospective partners. Competition may increase further because of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Decoy's competitors may develop, acquire or license drug products that are more effective or less costly than any product candidate Decoy may develop.

The programs Decoy is focusing on are in a preclinical stage and are targeted toward indications for which there are approved products on the market or product candidates in clinical development. Decoy will face competition from other drugs that are or will be approved for the same therapeutic indications. Decoy's ability to compete successfully will depend largely on its ability to leverage its experience in drug discovery and development to discover and develop therapeutics superior to other products in the market, attract and retain qualified scientific, product development and commercial personnel, obtain and maintain patent and/or other proprietary protection for its technology platform and product candidates, obtain required regulatory approvals faster than competitors, and successfully collaborate with third parties with respect to these endeavors.

The availability of Decoy's competitors' products could limit the demand, and the price Decoy can charge, for any products it may develop and commercialize. Decoy will not achieve its business plan if the acceptance of its products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to its products, or if physicians switch to other new drug products or reserve Decoy's products for use in limited circumstances. Additionally, the biopharmaceutical industry is characterized by rapid technological and scientific change, and Decoy may not be able to adapt to these rapid changes to the extent necessary to keep up with competitors or at all. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on Decoy's business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make Decoy's product candidates less competitive. Any new product that competes with an approved product must typically demonstrate advantages, such as in efficacy, convenience, tolerability or safety, to overcome price competition and to succeed. Decoy's competitors may obtain patent protection, receive approval by FDA and/or foreign regulatory authorities or discover, develop and commercialize product candidates before Decoy does, which would have a material adverse impact on its business.

Decoy's business could be negatively impacted by cybersecurity threats and other security threats and disruptions.

Because Decoy's business relies on proprietary data and related technology and computer systems, it faces certain security threats, including threats to its information technology infrastructure, attempts to gain access to its proprietary or confidential information, threats to physical security, and domestic terrorism events. Decoy's information technology networks and related systems are critical to the operation of its business and its research and development efforts. Decoy is also reliant on information technology systems operated by certain third parties, which generally face similar security threats and which third parties and their activities are beyond Decoy's control. Cybersecurity threats in particular, are persistent, evolve quickly and include, but are not limited to, computer viruses, attempts to access information, denial of service and other electronic security breaches. Decoy believes that it has implemented appropriate measures and controls and invested in skilled information technology resources to appropriately identify threats and mitigate potential risks, but there can be no assurance that such actions will be sufficient to prevent disruptions to critical systems, the unauthorized release of confidential information or corruption of data. A security breach or other significant disruption involving these types of information and information technology networks and related systems could:

- disrupt the proper functioning of these networks and systems and therefore its operations and/or those of third parties on which Decoy relies;
- result in the unauthorized access to, and destruction, loss, theft, misappropriation or release of, Decoy's proprietary, confidential, sensitive or otherwise valuable information, or that of third parties with which it collaborates or otherwise depends, which others could use to compete against Decoy or for disruptive, destructive or otherwise harmful purposes and outcomes;
- delay or compromise preclinical or clinical studies or the analysis and use of data collected in Decoy's efforts to develop product candidates;

- require significant attention and resources of management and key personnel to remedy any damages or other adverse consequences that result;
- subject Decoy to claims for breach of contract, damages, credits, penalties or termination with respect to its relationships with third parties, or regulatory actions by governmental agencies; and
- damage Decoy's reputation with industry participants, existing or prospective strategic alliances, and the public generally.

Certain of Decoy's operations may have bearing on pandemic preparedness, national security and homeland defense, which increases the threat of cybersecurity attacks or incidents and the potential for losses, liability and other adverse consequences Decoy could incur or experience as a result. Companies are increasingly suffering damage from attacks by hackers and there is a general risk that adversaries in geopolitical conflicts such as those taking place in Ukraine and in the Middle East adopt widespread Internet hacking as a weapon, which hacking may ultimately affect Decoy. In the ordinary course of business, Decoy stores sensitive information, such as its intellectual property, including trade secrets and results of its research, and that of its suppliers and business partners, using online systems, and such information is sometimes transmitted via email correspondence. The secure maintenance and processing of this information is critical to Decoy's research and development activities and future operations. Despite Decoy's security measures, its information technology and infrastructure may be vulnerable to attacks by hackers or breaches due to employee error, malfeasance or other disruptions. Any such unauthorized access, disclosure, misappropriation or other loss of information could result in disruption of Decoy's operations, including its existing and future research collaborations, and damage its reputation, which in its turn could harm its business and future results of operations. The data and software on which Decoy's technology depends, as well as other information used in its operations, are trade secrets which are critical to its business, and any loss or unauthorized access or use thereof could materially harm its business.

Further, Decoy is or may become subject to data privacy laws and regulations that could be implicated in its operations, including due to the issues described above. The interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. Among other things, federal, state and foreign privacy laws impose significant obligations on U.S. companies to protect the personal information of foreign and domestic citizens. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with Decoy's data practices, which could have a material adverse effect on its business. Complying with these various laws could cause Decoy to incur substantial costs or require Decoy to change its business practices in a manner adverse to its business.

Any of the foregoing events could have a material negative impact on Decoy's business, financial condition and prospects.

Failure of Decoy's information technology infrastructure to operate effectively could adversely affect its business.

Decoy depends on information technology infrastructure to pursue its business objectives and development efforts with respect to its product candidates. If a problem occurs that impairs this infrastructure, including as a result of an outage or malfunctioning of the hardware and software comprising or contributing to the information technology, the resulting disruption could impede Decoy's ability to proceed with research objectives in a timely manner, or otherwise carry on business in the normal course. Any such events could cause Decoy to lose opportunities or progress with respect to product candidates or strategic alliances, and could require Decoy to incur significant expense to remediate.

The commercial success of Decoy's product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

Assuming one or more product candidates achieve regulatory approval and Decoy commences marketing such products, the market acceptance of any product candidates will depend on several factors, including:

- demonstration of clinical safety and efficacy compared to other products;

- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any adverse effects or serious adverse effects;
- limitations on marketing or warnings in the label approved by FDA and/or foreign regulatory authorities for such products;
- the timing of market introduction of Decoy's products relative to competitive products and the availability of alternative treatments;
- pricing and cost-effectiveness;
- the execution and effectiveness of Decoy's or any partners' sales and marketing strategies;
- Decoy's ability to obtain hospital formulary approval; and
- Decoy's ability to obtain and maintain sufficient third-party payor coverage or reimbursement.

In addition, healthcare reform measures such as the ACA and future government initiatives could have the effect of reducing prices for products Decoy seeks to commercialize in the future, thereby reducing its prospects for revenue and profitability with respect to any such products.

If Decoy obtains regulatory approval for one product candidate, it expects sales to generate substantially all of its product revenues, and as such, the failure of such product to find market acceptance would adversely affect Decoy's results of operations.

Due to the change in the United States presidency, Decoy and its industry face uncertainty including the potential for adverse regulatory developments, which may adversely affect Decoy's business.

Decoy and its industry face uncertainty in regard to the regulatory environment Decoy will face as it proceeds with research and development, and possibly in the future commercialization, efforts following the election of the Republican presidential administration in November 2024. While much of the Trump Administration's proposed policies appear to be focused on deregulation, the new administration and federal government could adopt or further regulation or legislation that adversely affects Decoy or creates a more challenging or costly environment to pursue the development and sale of new therapeutic products. For example, because one major goal of the new administration will be to cut spending in the federal government, the FDA could as a result face staff reductions, which could result in delays or limitations on Decoy's ability to proceed with clinical programs and obtaining the requisite regulatory approvals in the future. Decoy also relies on federal grants for a portion of the funding for its research and development programs, which may be reduced or more difficult to access. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to Decoy's operations. Further, to the extent the federal government's policies and regulatory framework operates to favor Decoy's competitors, including larger pharmaceutical companies, more than Decoy in the future, it could limit Decoy's ability to obtain approval for or obtain or maintain a market presence and commercialize products in the future. If Decoy or its partners become negatively impacted by future government laws or regulations due to the changes in the federal government as a result of the election, it could have a material adverse effect on Decoy and its operating results, in which case you could lose all or most of your investment.

If Decoy is unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell its product candidates, Decoy may be unable to generate any revenues from product sales.

Decoy does not have a team with experience in the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, Decoy must build its sales, marketing, managerial and other non-technical capabilities or arrange with third parties to provide these services.

Decoy's current and future partners may not dedicate sufficient resources to the commercialization of Decoy's product candidates or may otherwise fail in their commercialization efforts due to factors beyond Decoy's control. If Decoy is unable to establish effective alliances to enable the sale of its product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by Decoy's own marketing and sales force, or if Decoy's potential future strategic partners do not successfully commercialize the product candidates, Decoy's ability to generate revenues from product sales will be adversely affected.

If Decoy is unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, it may not be able to generate sufficient product revenue and may not become profitable. Decoy will be competing with many companies that have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, Decoy may be unable to compete successfully against these more established companies.

If Decoy obtains approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect its business.

If any of Decoy's product candidates are approved for commercialization, Decoy may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. Decoy expects its will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could cause increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is endemic;
- the impact of any war or hostilities such as those occurring in Ukraine and the Middle East;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If Decoy loses key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in its compensation costs, its business may materially suffer.

Decoy depends on principal members of its executive and research teams; the loss of whose services may adversely impact the achievement of its objectives. Decoy is highly dependent on certain key personnel, particularly Frederick Pierce, its Chief Executive Officer, Peter Marschel, its Chief Business Officer, Barbara Hibner, its Chief Scientific Officer, and Michael Lipp, its Chief Technology Officer. If Decoy loses the services of any of these individuals, it may be unable to locate replacements capable of performing these roles effectively, and any such individual will require high compensation in a competitive market for experienced and qualified personnel within Decoy's industry. Decoy does not carry "key-man" life insurance on any of its employees or advisors. Furthermore, Decoy's future success will also depend in part on the continued service of its key scientific and management personnel and its ability to identify, hire, and retain additional personnel. Decoy may not be able to attract and retain personnel on acceptable terms, as there is significant competition among numerous pharmaceutical companies for

individuals with similar skill sets. Because of this competition, Decoy's compensation costs may increase significantly. If Decoy loses key employees, its business may suffer.

Any relationships with customers and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If Decoy is unable to comply, or have not fully complied, with such laws, it could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If Decoy obtains FDA approval for any of its product candidates and commercialize those products in the United States, its operations may be directly, or indirectly through its customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, Decoy's proposed sales, marketing and education programs. Decoy may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which Decoy conducts its business. The laws that may affect Decoy's ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009 , and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If Decoy's operations are found to violate any of the laws described above or any other governmental regulations that apply to Decoy, Decoy may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, and curtailment or restructuring of its operations, which could adversely affect its ability to operate its business and its results of operations.

Because Decoy will face potential product liability as it further develops product candidates and more so if it can commercialize any product candidate, if claims are brought against Decoy, it may incur substantial liability and costs.

Using Decoy's product candidates in clinical trials and the sale of any products for which it obtains marketing approval will expose Decoy to the risk of product liability claims. Product liability claims might be brought against Decoy by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with Decoy's products. These claims may allege that Decoy's products caused harm to them and/or that any adverse side effects or outcomes were not adequately disclosed or labelled. If Decoy cannot successfully defend

against product liability claims, it could incur substantial liability and costs. Regardless of merit or eventual outcome, product liability claims may cause:

- impairment of Decoy's business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from Decoy's primary business;
- substantial monetary awards to patients or other claimants;
- regulatory scrutiny and product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize Decoy's product candidates; and
- decreased demand for Decoy's product candidates, if approved for commercial sale.

Insurance coverage is becoming increasingly expensive and Decoy may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect Decoy against losses due to liability. If and when Decoy obtains marketing approval for product candidates, Decoy intends to expand its insurance coverage to include the sale of commercial products; however, Decoy may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Occasionally, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against Decoy could cause its stock price to decline and, if judgments exceed Decoy's insurance coverage, could adversely affect its results of operations and business.

If Decoy fails to comply with applicable laws and regulations, including environmental, health and safety laws and regulations, it could become subject to fines or penalties or incur costs that could have a material adverse effect on its business.

Decoy is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the treatment of animals used in research. Decoy's operations involve using hazardous and flammable materials, including chemicals and biological materials. Decoy's operations also produce hazardous waste products. Decoy generally contracts with third parties for the disposal of these materials and wastes. Decoy cannot eliminate the risk of contamination or injury from these materials. If contamination occurs or injury results from Decoy's use of hazardous materials, Decoy could be held liable for any resulting damages, and any liability could exceed its resources. Decoy also could incur significant costs associated with civil or criminal fines and penalties.

The Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to pathogens such as those Decoy aims to treat. These requirements, among other things, require work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that Decoy includes in its safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace.

Although Decoy's workers' compensation insurance may cover Decoy for costs and expenses, Decoy may incur additional costs due to injuries to its employees resulting from the use of hazardous materials or other work-related injuries, and this insurance may not provide adequate coverage against other potential liabilities. Decoy may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair Decoy's research, development or production efforts. Failure to comply with these laws and regulations also may cause substantial fines, penalties or other sanctions.

Business interruptions resulting from pandemics, natural disasters and adverse weather events could cause delays in research and development of Decoy's product candidates.

Decoy and third parties on which Decoy relies upon are vulnerable to natural disasters such as earthquakes, tornados, severe storms, hurricanes, tsunamis, and fires, as well as other events that could disrupt Decoy's operations and cause delays in research and development of its product candidates. Decoy does not carry insurance for natural disasters or similar events, and it may not carry sufficient business interruption insurance to compensate for losses that may occur. Any losses or damages Decoy incurs could have a material adverse effect on its operations.

USE OF PROCEEDS

Salarius estimates that the net proceeds from the sale of securities in this offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by Salarius. If the underwriters exercise the over-allotment option in full, Salarius estimates that its net proceeds will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by Salarius.

Salarius' expected use of the net proceeds from this offering represents Salarius' current intentions based upon its present plans and business condition and the proposed plans of the combined company. As of the date of this prospectus, Salarius cannot predict with certainty all of the particular uses for the net proceeds to be received upon completion of this offering, or the amounts that Salarius will actually spend on the uses set forth above. However, Salarius currently intends to use the net proceeds to Salarius from this offering primarily for general corporate purposes, including working capital, research and development, and capital expenditures, although Salarius does not currently have any specific or preliminary plans with respect to the use of proceeds for such purposes. Pending the uses described above, Salarius intends to invest the net proceeds from this offering in short term, interest-bearing securities such as money market accounts, certificates of deposit, commercial paper, or direct or guaranteed obligations of the U.S. government.

Based on the proposed plans of the combined company, Salarius believes its existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund Salarius's operating expenses and capital expenditure requirements through the first quarter of 2026.

The amounts and timing of Salarius' actual use of the net proceeds will vary depending on numerous factors, including Salarius' ability to gain access to additional financing and the relative success and cost of Salarius' research and development programs. As a result, Salarius' management will have broad discretion in the application of the net proceeds, and investors will be relying on Salarius' judgment regarding the application of the net proceeds of this offering. In addition, Salarius might decide to postpone or not pursue certain development activities if the net proceeds from this offering and any other sources of cash are less than expected.

MARKET PRICE INFORMATION

Salarius' common stock is listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "SLRX."

On January 17, 2025, the last reported sale price for Salarius' common stock on Nasdaq was $2.69 per share. As of January 14, 2025, Salarius had approximately 139 stockholders of record. The actual number of holders of Salarius' common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Currently, there is no public market for the pre-funded warrants offered hereunder. Salarius does not intend to list the pre-funded warrants on Nasdaq or any other national securities exchange or nationally recognized trading system. Salarius cannot predict the extent to which investor interest in Salarius will lead to the development of an active trading market in such pre-funded warrants or how liquid that market might become.

Assuming successful application for listing on the Nasdaq Capital Market, following the consummation of the Merger, Salarius' common stock will trade on the Nasdaq Capital Market under the new name, "Decoy Therapeutics, Inc."

DIVIDEND POLICY

Salarius does not expect to pay any cash dividends to its stockholders in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of Salarius' board of directors and will depend on a number of factors, including Salarius' results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law, and other factors Salarius' board of directors of directors deems relevant.

CAPITALIZATION

The following table sets forth Salarius' capitalization as of September 30, 2024:

- on an actual basis;
- on a pro forma basis to give effect to the issuance of ------shares of Salarius' common stock subsequent to September 30, 2024 through ------, 2025; and
- on a pro forma as adjusted basis, giving effect to (i) the issuance and sale of $ shares of Salarius' common stock (or pre-funded warrants in lieu of common stock) in this offering at an assumed public offering price of $ per share, which is the last reported sales price of Salarius' common stock on the Nasdaq Capital Market on , 2025, assuming no sale of any pre-funded warrants after deducting the estimated underwriter fees and estimated offering expenses payable by Salarius; and (ii) the issuance of an estimated ------ shares of Salarius' Common Stock at the Merger Closing and (ii) the issuance of an estimated ------ shares of Salarius' Common Stock assuming conversion of an estimated ------ shares of Series A Preferred Stock to be issued at the Merger Closing, convertible at a ratio of 1:1,000.

The pro forma information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined at pricing.

You should read the following table in conjunction with the section titled "*Use of Proceeds*" in this prospectus and the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations of Salarius*" and Salarius' consolidated financial statements and related notes thereto included in this registration statement of which this prospectus forms a part for the three and nine months ended September 30, 2024.

	As of September 30, 2024 (Unaudited)		
	Actual	Pro Forma	Pro Forma as Adjusted
Cash and cash equivalents	$ 3,284,029	$ —	$ —
Stockholders' equity			
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2024, actual, pro forma and adjusted pro forma; 0 issued and outstanding as of September 30, 2024, actual,0 issued and outstanding as of September 30, 2024, pro forma, and ------shares issued and outstanding as of September 30, 2024, pro forma as adjusted	—	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized as of September 30, 2024 actual, pro forma, and adjusted pro forma, 1,441,157 shares issued and outstanding as of September 30, 2024, actual, ------shares issued and outstanding as of September 30, 2024, proforma, and shares issued and outstanding as of September 30, 2024, pro forma as adjusted	144	—	—
Additional paid-in capital	83,384,124	—	—
Accumulated deficit	(80,459,685)	—	—
Total stockholders' (deficit) equity	2,924,583	—	—
Total capitalization	$ 3,859,164	$ —	$ —

The number of shares of common stock, pro forma in the table above, is based on an aggregate of 1,441,157 shares of Salarius' common stock outstanding as of September 30, 2024, which is then adjusted for the issuance of

shares of common stock subsequent to September 30, 2024 for an aggregate of ---- outstanding and excludes the following:

- 31,554 shares of Salarius' common stock issuable upon the exercise of stock options outstanding as of September 30, 2024 at a weighted-average exercise price of $66.75 per share;
- 131 shares of Salarius' common stock issuable upon the settlement of restricted stock units outstanding as of September 30, 2024;
- 1,015,385 shares of Salarius' common stock issuable upon the exercise of warrants outstanding as of September 30, 2024 at a weighted average exercise price of $24 per share;
- 9,844 shares of Salarius' common stock available for future issuance under the 2015 Equity Incentive Plan as of September 30, 2024;
- 25,501 shares of Salarius' common stock reserved for future issuance under the 2015 Employee Stock Purchase Plan as of September 30, 2024; and
- ------ shares of Salarius' common stock issuable upon the exercise of the representative warrants issued as compensation to the representative in this offering.

DILUTION

If you invest in Salarius' securities in this offering, your interest will be diluted immediately to the extent of the difference between the public offering price and the pro forma as adjusted net tangible book value per share of Salarius' common stock after this offering.

Salarius' net tangible book value on September 30, 2024, was approximately $2.9 million, or $2.00 per share. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding.

Salarius' pro forma net tangible book value as of September 30, 2024 was $------ million, or $------ per share. Pro forma net tangible book value represents total tangible assets, exclusive of intangible assets and goodwill, less total liabilities, after giving effect to the issuance of ------ shares of Salarius common stock subsequent to September 30, 2024 through ------, 2025. Pro forma net tangible book value per share represents Salarius' pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2024, after giving effect to the pro forma adjustment described above.

Pro forma as adjusted net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of Salarius' common stock in this offering and the pro forma as adjusted net tangible book value per share of Salarius' common stock immediately after completion of this offering and the Merger Closing. After giving effect to (i) the sale by Salarius in this offering of shares of its common stock at a public offering price of $ per share of common stock, which was the last reported sale price of Salarius' common stock on the Nasdaq Capital Market on , 2025 and the cash exercise of pre-funded warrants to purchase shares of its common stock, and no exercise by the underwriter of the over-allotment option, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses that Salarius' will pay and (ii) the issuance of an estimated ------ shares of Salarius' common stock assuming conversion of an estimated shares of Series A Preferred Stock to be issued at the Merger Closing, convertible at a ratio of 1:1,000, Salarius' pro forma as adjusted net tangible book value as of September 30, 2024 would have been approximately $ million or $ per share of common stock. This amount represents an immediate increase in net tangible book value of $ per share to existing shareholders and an immediate dilution of $ per share to investors in this offering.

Assumed public offering price		$
Net tangible book value per share as of September 30, 2024	$ 2.00	
Decrease per share attributable to the pro forma adjustments described above	$	
Pro forma net tangible book value per share as of September 30, 2024	$	
Increase per share attributable to new investors in this offering		
Pro forma as adjusted net tangible book value per share after giving effect to the offering and the Merger Closing		$
Dilution per share to new investors purchasing securities in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual public offering price and other terms of this offering determined at pricing.

The number of shares of common stock, pro forma in the table above, is based on an aggregate of 1,441,517 shares of Salarius' common stock outstanding as of September 30, 2024, which is then adjusted for the issuance of------shares of common stock subsequent to September 30, 2024 for an aggregate of ------outstanding, and excludes the following:

- 31,554 shares of Salarius' common stock issuable upon the exercise of stock options outstanding as of September 30, 2024 at a weighted-average exercise price of $66.75 per share;
- 131 shares of Salarius' common stock issuable upon the settlement of restricted stock units outstanding as of September 30, 2024;

- 1,015,385 shares of Salarius' common stock issuable upon the exercise of warrants outstanding as of September 30, 2024 at a weighted average exercise price of $24 per share;
- 9,844 shares of Salarius' common stock available for future issuance under the 2015 Equity Incentive Plan as of September 30, 2024;
- 25,501 shares of Salarius' common stock reserved for future issuance under the 2015 Employee Stock Purchase Plan as of September 30, 2024; and
- ------ shares of Salarius' common stock issuable upon the exercise of the representative warrants issued as compensation to the representative in this offering.

To the extent that outstanding options have been or may be exercised or other shares issued, investors in this offering may experience further dilution. In addition, Salarius may choose to raise additional capital due to market conditions or strategic considerations even if Salarius believes it has sufficient funds for Salarius' current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to Salarius' stockholders.

SALARIUS' BUSINESS

Overview of Salarius Business

Salarius is a clinical-stage biopharmaceutical company focused on developing treatments for parties with cancers with high, unmet medical need. Specifically, Salarius is concentrated on developing treatments for cancers caused by dysregulated gene expression, i.e., genes which are incorrectly turned on or off. Salarius has two classes of drugs that address gene dysregulation: protein inhibitors and targeted protein degraders. Salarius' technologies have the potential to work in both liquid and solid tumors. Salarius' current pipeline consists of two small molecule drugs: 1) SP-3164, targeted protein degrader, and 2) seclidemstat ("SP-2577"), a targeted inhibitor. Salarius is located in Houston, Texas.

Program Development

SP-3164 – Targeted Protein Degradation

The field of targeted protein degradation (TPD) is rapidly growing. The two most common types of protein degraders are molecular glues ("MGs") and proteolysis-targeting chimeras (PROTACs). SP-3164 is a next-generation cereblon-binding MG.

MGs are small molecules that commandeer the body's normal protein degradation processes by causing proteins to stick to one another thereby inducing selective degradation of cancer-causing proteins. Derived from avadomide, SP-3164 is engineered using deuterium-enabled chiral switching , a process that replaces hydrogen atoms with deuterium to stabilize the molecule's active enantiomer, resulting in a novel molecular entity with the potential for increased efficacy and improved safety compared to the first generation compound. SP-3164 degrades transcription factors IKZF1 ("Ikaros") and IKZF3 ("Aiolos"), along with other proteins, resulting in both direct anti-cancer activity and immune-modulating properties.

Salarius' plan had been to develop SP-3164 in high unmet need hematological indications and solid tumors. Salarius' goal was to file an investigational new drug ("IND") application with the United States Food and Drug Administration ("FDA") for SP-3164 in the first half of 2023, and begin a Phase 1/2 clinical trial in the second half of 2023, however the lack of funding required Salarius to curtail spending necessary to begin the clinical trial program. The combined company plans to integrate Salarius' assets, particularly the proprietary compound SP-3164, to expand its opportunities in creating a novel class of peptide conjugates called peptide-based proteolysis targeting chimeras (PPROTACs).

SP-2577 Ewing Sarcoma

Ewing sarcoma is a devastating pediatric and young adult cancer for which there are no approved targeted therapies. The cause of Ewing sarcoma is a chromosomal translocation involving the Ewing sarcoma breakpoint region 1 gene and ETS family genes, resulting in expression of a fusion oncoprotein. The resulting oncoprotein has been found to co-localize with LSD1 throughout the genome, making LSD1 an attractive therapeutic target for Ewing sarcoma.

On July 19, 2024, Salarius' announced it had determined to close its ongoing Phase ½ clinical trial evaluating SP-2577 for Ewing sarcoma, including closing the remaining clinical trial sites.

SP-2577 Myelodysplastic Syndromes And Chronic Myelomonocytic Leukemia

Salarius intends to continue supporting The University of Texas MD Anderson Cancer Center ("MDACC") in MDACC's sponsored investigator-initiated clinical trial evaluating SP-2577 in combination with azacitidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia. The trial remains on partial clinical hold following a serious and unexpected grade 4 adverse event while MDACC works with the FDA to resolve the partial clinical hold. The combined company intends to conduct a thorough review of this small molecule program in early 2025.

Strategic Agreements

Listed below are the strategic agreements that may have an impact on Salarius' results of operations and which are expected to be evaluated by the combined company following the consummation of the Merger.

The University of Utah Research Foundation

On August 3, 2011, Salarius entered into an Exclusive License Agreement with the University of Utah Research Foundation (the "University of Utah"), for the exclusive license with respect to patent rights protecting SP-2577 and related compounds. The patent rights were for a provisional patent. The term of the agreement is until the last-to-expire of the patent rights licensed under the agreement, which is expected to be as late as 2037, unless otherwise terminated by law or by the parties pursuant to the agreement.

In further consideration of the rights granted by the University of Utah, Salarius agreed to pay all past patent expenses incurred in filing and prosecuting the patent application, and pay all future patent expenses incurred including filing, prosecuting, enforcing and maintaining the patent right.

Under the terms of the agreement, Salarius may be obligated to make certain future milestone and royalty payments, including: (i) an earned royalty payment based on a single digit percentage of net sales and a required minimum annual royalty payment commencing with the third full calendar year after the first commercial sale in the United States, Germany, France, Japan or the U.K. ranging from $10,000 to $40,000 per year which minimum payments are fully creditable towards the earned royalty payment with respect to the relevant calendar year, (ii) a sublicensee fee based on a single digit percentage of revenues received by sublicensees, (iii) milestone payments in agreed dollar amounts upon receiving regulatory approvals allowing the marketing and sale of licensed products or licensed methods relating to the patients' rights in each of the United States, the European Union and Japan not exceeding $150,000 in the aggregate and (iv) a milestone payment in an agreed dollar amount upon the two year anniversary of the first commercial sale of a licensed product not exceeding $1.0 million.

Either party has a right to terminate the agreement for a breach of or default under the agreement following a 60-day cure period. If Salarius ceases to carry on its business with respect to the patent right granted under the agreement, the University of Utah has a right to terminate the agreement upon 60 days' notice. In addition, Salarius may terminate the agreement at any time upon ninety days' notice to the University of Utah.

Cancer Prevention and Research Institute of Texas

In June 2016, Salarius entered into a Cancer Research Grant Contract with Cancer Prevention and Research Institute of Texas ("CPRIT"). The grant contract was for an amount up to $18.7 million to fund the development of LSD-1 inhibitor. The grant was subsequently amended to remove $2.6 million related to a discontinued prostate cancer program. Salarius received approximately $16 million under the grant. The grant has been closed as of December 31, 2023.

DeuteRx, LLC

On January 12, 2022, Salarius entered into an acquisition and strategic collaboration agreement (the "ASCA") with DeuteRx, LLC ("DeuteRx"), pursuant to which Salarius acquired targeted protein development portfolio.

The portfolio was purchased for an aggregate purchase price of $1.5 million and the delivery of 40,000 shares of Salarius' common stock. Salarius agreed to pay to DeuteRx (i) milestone payments upon the occurrence of certain events and (ii) royalty payments. A member of Salarius' board of directors also serves as a consultant to DeuteRx and is a consultant to an affiliate of DeuteRx.

Simultaneously with Salarius entry into the ASCA, Salarius and DeuteRx entered into the R&D Services Agreement, which sets forth the terms and conditions upon which DeuteRx will provide services to Salarius, including the implementation and performance of a Non-Clinical and Clinical Development Scope of Work. The ASCA remains in place, albeit at lower service levels resulting from company-wide cost cutting measures.

Manufacturing, Sales and Marketing

Salarius currently has no manufacturing facilities, nor does it have a sales and marketing organization because Salarius' product candidates are still in preclinical or early-stage clinical development.

Intellectual Property

Salarius' patent portfolio includes composition of matter and methods of use patents on Salarius' candidate, SP-2577. In the United States, Salarius has two composition of matter patents and one methods of use patent with respect to SP-2577 and related compounds which will expire in 2032. The patents and patent applications related to SP-2577 are owned by the University of Utah Research Foundation and are exclusively licensed to Salarius.

Salarius also has patents with claims that cover the composition of matter of SP-3164 with a patent term expiration of January 14, 2034.

As of January 14, 2025, the targeted degradation patent portfolio consisted of 6 patent families with 17 granted patents and 4 pending applications acquired in the DeuteRx Transaction

In addition to patent protection, Salarius seeks to rely on trade secret protection, trademark protection and know-how to expand its proprietary position around its chemistry, technology and other discoveries and inventions that Salarius considers important to its business. Salarius also seeks to protect its intellectual property in part by entering into confidentiality agreements with employees, consultants, scientific advisors, clinical investigators and other contractors and by requiring employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant Salarius ownership of any discoveries or inventions made by them. Further, Salarius seeks trademark protection in the United States and internationally where available and when Salarius deems appropriate.

Competition

SP-3164: Targeted Protein Degradation and Competitive Differentiation

The field of TPD is rapidly growing and attracting a lot of interest from the biggest pharmaceutical companies. The two most common types of protein degraders are molecular glues ("MGs") and proteolysis-targeting chimeras (PROTACs). SP-3164 is a next-generation CRBN-binding MG. There are several MGs in clinical development and additional compounds in IND-enabling studies.

SP-2577: LSD1 Inhibition and Competitive Differentiation

LSD1 is a widely published epigenetic target and has attracted interest from several large pharmaceutical companies. LSD1 helps drive cancer progression through demethylation of histones and by acting as a scaffolding protein within various activator and repressor complexes.

Salarius believes that SP-2577 is differentiated in its ability to effectively inhibit LSD1's scaffolding properties in addition to LSD1's demethylation activity. Compared to irreversible LSD1 inhibitors, Salarius' molecule has a novel binding mechanism (reversible as opposed to irreversible) and binding location (closer to substrate binding site as opposed to the FAD cofactor of LSD1).

Government Regulation and Product Approvals

United States Government Regulation

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, the FDA's implementing regulations, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, quality control, safety, effectiveness, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Salarius cannot market a drug product candidate in the United States until the drug has received FDA approval.

Drug Development Process

The process required before a drug may be marketed in the United States generally include the following:

- completion of extensive non-clinical laboratory tests and animal studies in accordance with the FDA's good laboratory practices ("GLP") regulations, applicable requirements for the humane use of laboratory animals, such as the Animal Welfare Act or other applicable regulations;
- submission to the FDA of an IND for human clinical testing, which must be deemed effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") overseeing each clinical site before each trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCP") requirements, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a NDA for marketing approval that includes substantial evidence of safety and effectiveness from results of clinical trials, as well as the results of preclinical testing, detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product candidate;
- consideration by an FDA Advisory Committee, if applicable;
- satisfactory completion of potential FDA audits of the preclinical study and clinical trial sites that generated the data in support of the NDA;
- satisfactory completion of an FDA pre-approval inspection of the nonclinical, clinical and/or manufacturing sites or facilities at which the active pharmaceutical ingredient and finished drug product are produced and tested to assess compliance with current good manufacturing practices ("cGMP"); and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States, including agreement on post-marketing commitments, if applicable.

Before testing any drugs with potential therapeutic value in humans, the drug enters the preclinical testing stage. Pre-clinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including GLP and the Animal Welfare Act.

Before commencing the first clinical trial in humans, an IND must be submitted to the FDA, and the IND must become effective. An IND sponsor must submit the results of pre-clinical testing to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin if all other requirements, including IRB review and approval, have been met. If the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Even after the IND has gone into effect and clinical testing has begun, the FDA may also impose clinical holds on clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with state and federal

regulations, including GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, including stopping rules that assure a clinical trial will be stopped if certain adverse events ("AEs") should occur. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB, for approval of each site at which the clinical trial will be conducted. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www.clinicaltrials.gov website.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, safety and side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a larger but limited patient population to study metabolism of the drug, pharmacokinetics, the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials, also called pivotal trials, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication. The FDA has express statutory authority to require post-market clinical studies to address safety issues.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected AEs, any findings from other studies, tests in laboratory animals or in vitro testing and other sources that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

In limited circumstances, the FDA also permits the administration of investigational drug products to patients under its expanded access regulatory authorities. Under the FDA's expanded access authority, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the biological product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. Additionally,

appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Process

After completion of the required clinical testing, a sponsor may prepare and submit an NDA to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all non-clinical, clinical and other testing and a compilation of data relating to the product's toxicology, pharmacology, chemistry, manufacture and controls. In addition, under the Pediatric Research Equity Act, as amended, an NDA or supplement to an NDA generally must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers depending on the designated pathway for submission. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. These fees are typically increased annually. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Under the Prescription Drug User Fee Act performance goals that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA, because the FDA has approximately two months to make a "filing" decision. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to six months of the "filing" date for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Within 60 days following submission of the application, the FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may issue a refuse-to-file letter and request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility(ies) in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee-typically a panel that includes clinicians and other experts-for consideration, discussion and a vote on specific questions relevant to the approval decision. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP requirements is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

During the NDA review process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required. A REMS could include a medication guide, communication plan or elements to assure safe use, such as required healthcare provider or pharmacy certification, a patient registry and other safe use conditions.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data, or information, in order to resubmit the application for another cycle of FDA review. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the complete response letter, or withdraw the application. If those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post- approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS to ensure that the benefits of the drug outweigh the potential risks. The requirement for a REMS can materially affect the potential market and profitability of the drug. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, FDA determines the risk outweighs the benefits of the product or other problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs. Such supplements are typically reviewed within ten months of receipt or six months of receipt for priority efficacy supplements.

Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Although there may be some increased communication opportunities, orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a drug candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

As in the United States, designation as an orphan drug for the treatment of a specific indication in the European Union, must be made before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to ten years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

The FDA and foreign regulators expect holders of exclusivity for orphan drugs to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan drug.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for development and review of new drug products that meet certain criteria. Specifically, new drug products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the

combination of the product and the specific indication for which it is being studied. The sponsor of a new drug may request that the FDA designate the drug as a fast track product at any time during the clinical development of the product. For a fast track-designated product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. Fast track designation may be rescinded if FDA determines the program no longer meets the qualifying criteria for fast track.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval.

Additionally, a product may be eligible for accelerated approval under subpart H if it treats a serious or life-threatening disease or condition, provides meaningful advantage over existing treatments, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit or on an intermediate clinical endpoint. If a product qualifies for accelerated approval, the product may be approved based on an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict the drug's clinical benefit. As a condition of accelerated approval, the FDA will require that a sponsor of a drug product subject to accelerated approval perform an adequate and well-controlled post-marketing clinical trial to confirm clinical benefit. If a sponsor fails to conduct any required post-approval trial with "due diligence" FDA may withdraw the drug from the market. In addition, the FDA currently requires as a condition for accelerated approval that promotional materials be submitted in advance of initial dissemination, which could adversely impact the timing of the commercial launch of the product.

In addition, under the provisions of the FDA Safety and Innovation Act, the FDA established the breakthrough therapy designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of fast track designation, as well as more intensive FDA interaction and guidance. The Breakthrough therapy designation is distinct from both accelerated approval and priority review, but these can also be granted to the same product candidate if the relevant criteria are met. The FDA may take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Requests for breakthrough therapy designation will be reviewed within sixty days of receipt, and the FDA will either grant or deny the request. Breakthrough therapy designation may be rescinded if the FDA determines the program no longer meets the qualifying criteria for breakthrough therapy.

Fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if Salarius receives fast track or breakthrough designations for its product candidates, the FDA may later decide that its product candidates no longer meet the conditions for qualification. In addition, these designations may not provide Salarius with a material commercial advantage.

Post-Approval Requirements

Once an NDA is approved, a product is subject to extensive continuing post-approval requirements. Any drug products manufactured or distributed by Salarius pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. For example, as a condition of approval of the NDA, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS or other surveillance to monitor the effects of an approved product, or restrictions on the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects' entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters, warning letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals; and
- product seizure or detention, or refusal to permit the import or export of products; or injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Other Healthcare Laws

Although Salarius currently does not have any products on the market, Salarius' current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which Salarius conducts its business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine laws. Some of Salarius pre-commercial activities are subject to some of these laws.

Facilities

Salarius principal executive offices are in the Texas Medical Center in Houston, Texas, under a month-to-month lease. Currently, this facility consists of approximately 300 square feet and accommodates Salarius general and administrative activities. Salarius believes that its leased facility is adequate to meet its current needs.

Employees and Human Capital Resources

As of January 14, 2025, Salarius had 2 full-time employees and one part-time consultant serving as its Chief Executive Officer. Salarius has never had a work stoppage, and none of its employees are represented by a labor organization or under any collective bargaining arrangements. Salarius considers its employee relations to be good.

Legal Proceedings

Salarius is not currently a party to any legal proceedings the outcome of which Salarius believes, if determined adversely to Salarius, would individually or in the aggregate, have a material adverse effect on Salarius' business, financial condition, or results of operations. From time to time, Salarius may become involved in legal proceedings arising in the ordinary course of business.

Corporate Information and Web Site Access to SEC Filings

Salarius was initially incorporated as Flex Pharma, Inc. in Delaware in February 2014. In July 2019, Salarius changed its name to Salarius Pharmaceuticals, Inc. Salarius' principal executive offices are located at 2450 Holcombe Blvd., Suite X, Houston, TX 77021. Salarius' website address is www.salariuspharma.com. The public can obtain any documents that Salarius files with the SEC at http://www.sec.gov.

DECOY'S BUSINESS

Overview of Decoy's and the Combined Company's Proposed Business

Decoy's proprietary Immediate Peptide/PPMO/P-PROTAC Alpha-helical Conjugate Technology platform ("IMP^{3}ACT^{TM}") represents a paradigm shift in peptide conjugate drug discovery and manufacturing, leveraging machine learning ("ML") and artificial intelligence ("AI") tools alongside high- speed synthesis techniques to rapidly engineer, optimize and manufacture peptide conjugates that target serious unmet medical needs. Peptide conjugates are emerging as a major therapeutic drug modality, with the potential to transform multiple therapeutic areas. This innovative class of drugs, exemplified by successful diabetes and weight loss treatments like Ozempic, Wegovy, Mounjaro and ZepBound, combines small α-helical peptides with functional moieties to enhance solubility and extend the duration of action. By decreasing the complexity of peptide conjugate development, Decoy aims to establish itself as a leader in this advancing drug class. Decoy's goal is to build a robust portfolio of novel peptide conjugate therapeutics, initially focusing on infectious diseases and oncology. Through this approach, Decoy intends to revolutionize the design, development, and commercialization of peptide conjugate therapeutics, becoming a fully integrated biopharmaceutical company at the forefront of this exciting field.

The peptide conjugate drug class is extremely modular and flexible, making it applicable to a wide range of human disease states and medical indications. Decoy expects that its drug candidates may be used both chronically, like current diabetes or weight loss drugs, or acutely, as is typical of antiviral treatments. Decoy is planning to engineer its peptide conjugates to be delivered via a variety of routes that can be optimally matched to the targeted disease state, including intranasal and pulmonary inhalation, extended-release dermal patches, oral, subcutaneous injection, and intravenous. Peptide drug conjugates can also be designed to deliver payloads, including radionucleotides or approved small molecule or biological drugs, to a specific target or tissue of interest, such as cancerous tumors, to achieve highly precise delivery with increased tissue penetration and lower cost compared to antibody-drug conjugates ("ADCs"). As with ADCs, the goal of this strategy is to widen the "therapeutic window" by increasing efficacy while reducing the overall dose and consequent side-effects of the payload. Decoy believes the peptide conjugate modality is ideally suited to this strategy. Decoy believes its integration with Salarius expands the combined company's opportunities to create an additional novel class of peptide conjugates, specifically, peptide-based proteolysis targeting chimeras ("P-PROTACs"), utilizing the Salarius compound SP-3164 as an important building block in these peptide conjugate drugs.

New Program Development in the Merged Company

The combined company intends to leverage Salarius' proprietary compound SP-3164, which specifically binds to the E3 ligase complex CRL^{CBRN}, together with Decoy's peptide engineering platform to engineer peptides to target a variety of disease relevant intracellular proteins, creating 'peptide based-Proteolysis Targeting Chimeras,' or PROTACs (P-PROTACS).

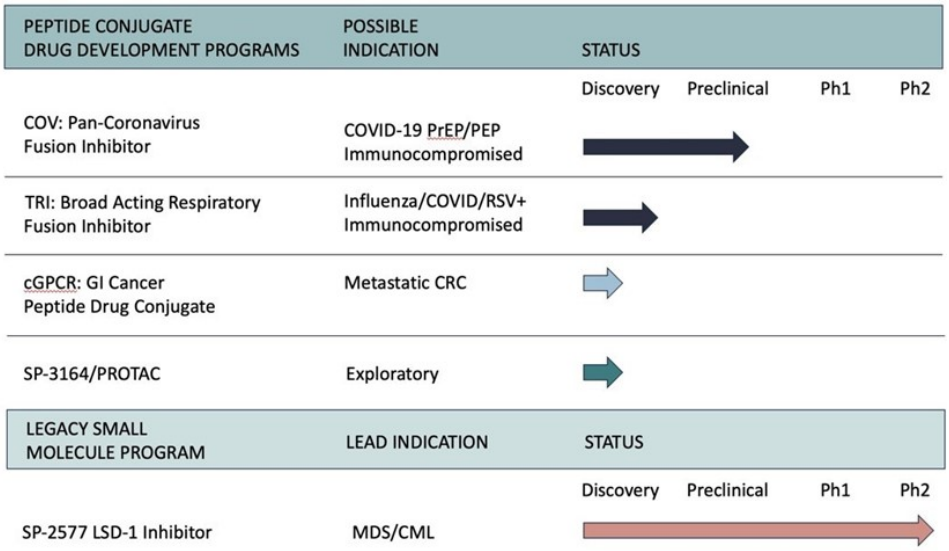
PROTACs are typically a bifunctional molecule; one side of the molecule binds to a targeted protein, while the other side of the molecule binds to an E3 ligase, with a linker between the two. When both the targeted protein and the E3 ligase are brought together the targeted protein is ubiquitinated, or "tagged" by the E3 ligase, and is marked for destruction via proteasomal protein degradation. SP-3164, a novel and proprietary immunomodulatory drug molecule, has many advantageous properties including potent cereblon binding, low molecular weight, high oral bioavailability, and clear and well characterized binding mechanisms. Using the IMP^{3}ACT platform engineered peptides instead of small molecules to target disease causing proteins has many advantages: peptides can be precisely engineered to bind specifically to one protein, or to a pre-determined set of proteins (for example, across mutated Ras proteins). In contrast, small molecules typically bind to many "off-target" proteins, decreasing selectivity and increasing toxicity. Peptides can bind to the active enzymatic site of a protein but can also be engineered to bind to other sites on the protein which may be under much lower selective mutational pressure, lowering the likelihood of resistance mechanisms and avoiding competition with the natural ligand. Finally, Decoy believes using peptides instead of existing small molecules vastly expands the protein targeting opportunities, and dramatically shortens the timelines to engineering P-PROTAC candidates.

The PROTAC mechanism of action can be described as "event-driven" in which one PROTAC molecule can induce the degradation of multiple copies of the protein target. Even small concentrations of the PROTAC can be highly advantageous, such that toxicity due to high drug concentrations may be avoided. Additionally, by degrading rather than inhibiting the protein target, both enzymatic and any other functions of the protein are disrupted, and these effects will last for as long as it takes the cell to synthesize new proteins, which can dramatically expand the duration of action of even a small concentration of a PROTAC. Thus, the combined company's P-PROTACs may be ideal peptide drug conjugate payloads, targeting a potentially wide range of intracellular biologically relevant targets, including those thought to be "undruggable," and representing a major addition to Decoy's IMP^{3}ACT platform. Upon consummation of the Merger, this is expected to become a major focus of exploratory research at the combined company, with an initial focus on creating P-PROTACs for metastatic colorectal cancer to complement Decoy's colorectal cancer G protein-coupled receptor-based ("GPCR") peptide conjugate program.

Decoy's Drug Development Programs

Decoy is developing peptide conjugates and peptide-PROTACs with an initial focus on the treatment of viral infections and colorectal cancer. Decoy has demonstrated multi-virus in vitro activity with direct acting peptide conjugate antivirals by targeting the highly conserved fusion mechanism found across enveloped virus families. Next, Decoy intends to apply the same peptide design ML/AI tools to create peptide binders to select overexpressed G protein-coupled receptor colorectal cancer targets for novel precision medicine peptide drug conjugates. Decoy intends to explore the use of the Salarius compound SP-3164, a molecular glue degrader that binds to cereblon, as a building block in a P-PROTAC in which the combined company plans to engineer a peptide targeting a protein of interest in colorectal cancer. This P-PROTAC may be suitable as a novel and proprietary payload for Decoy's colorectal targeting peptide conjugate.

Through Decoy's IMP^{3}ACT Platform the combined company would aim to create a diverse and growing development portfolio of peptide conjugate, PDC and P-PROTAC programs as summarized in the figure below.



- ***COV: Pan-Coronavirus* Prophylactic for Immunocompromised Patients.** Decoy's lead program, a nasally inhaled *pan-Coronavirus* prophylactic, has demonstrated activity *in vitro* against all human infecting Coronaviruses tested, including representatives of all variant strains of concern of COVID-19 that have emerged as of the date of prospectus. This program has primarily been funded by grants from the Bill & Melinda Gates Foundation, the Center for the Biologic Advanced Research and Development Authority's Blue Knight Program ("BARDA"), and with additional support from the IMI Care Consortium, Google and NVIDIA computing programs. Decoy plans to file an IND for this program in the first half of

2026. Decoy intends to continue to pursue non-dilutive funding and a development partner for this program's clinical development.

- **TRI: Broad Respiratory Antiviral (Flu/COVID-19/Respiratory Syncytial Virus).** Decoy's goal is to exploit structural similarities across these viruses and their viral families to create a peptide conjugate antiviral that will be broadly applicable to most influenza-like-illnesses ("ILI"), which drive an estimated 15 to 20 million medical visits every year in the United States alone. Building on work that Decoy has already done to create peptide conjugate antivirals with very broad activity in the *Coronavirus* and *Paramyxovirus* (RSV) viral families, Decoy believes this program could represent a fundamental shift in the treatment of respiratory viruses.

- **cGPCR: GPCR-Targeted Conjugate for Colorectal ("CRC") and other Gastrointestinal ("GI") Tumors.** There is an urgent need for the identification of new cell membrane targets to create multiple precision treatment options for many colon cancer patients, including those with late stage metastatic and drug resistant tumors. Decoy aims to investigate an under-utilized cell membrane molecule class, the GPCRs as new precision medicine targets for Decoy's peptide engineering platform, ultimately creating novel peptide drug conjugates as new biomarker driven CRC therapeutics.

The Combined Company's Exploratory Stage Program

- **P-TAC: Exploratory P-PROTAC Conjugates**: The combined company would aim to explore the use of SP-3164 as the E3 ligase binding component in peptide based PROTACs, using engineered peptides to target intracellular proteins involved in colorectal cancer cell function and dysregulation.

Legacy Small Molecule Program resulting from the Merger

- **SP-2577**: SP-2577 is a legacy small molecule LSD-1 inhibitor program from Salarius not using Decoy technology. The combined company would intend to continue supporting The University of Texas MD Anderson Cancer Center ("MDACC") in MDACC's sponsored investigator-initiated clinical trial evaluating seclidemstat (SP-2577) in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia. The trial remains on partial clinical hold following a serious and unexpected grade 4 adverse event while MDACC works with the U.S. Food and Drug Administration ("FDA") to resolve the partial clinical hold. The combined company would intend to conduct a thorough review of this small molecule program in early 2025.

Strategy

Decoy's strategy is to leverage its IMP^{3}ACT platform to rapidly design, develop and commercialize novel and transformative peptide conjugate therapeutics that improve the lives of patients with serious diseases. Decoy's initial focus is on 3 types of peptide conjugates: fusion inhibitor peptide conjugates for viral diseases, GPCR-based peptide drug conjugates, and peptide-PROTACs. These areas were chosen as Decoy's starting points for the following reasons:

- The fusion inhibition machinery is highly conserved across all enveloped viruses, and peptide conjugate inhibitors offer a new antiviral modality in a therapeutic area with high medical need and low competition.

- GPCRs are a very rich target space that are simultaneously implicated in multiple serious disease states and have been underexploited in cancer. Peptide drug conjugates offer the potential for significant benefits including high tumor penetration, tissue selectivity with an improved toxicity profile, and are highly amenable to manufacturing modularity in payload type.

- PROTACs are an emerging drug class that suffers from two things: limitations due to what small molecules are available to target proteins of interest, and toxicity due to lack of selective tissue targeting. Peptide conjugate peptide-PROTACs can address both issues, dramatically expanding the range of the proteins of interest targeted for degradation and selectively targeting tissues for improved safety and efficacy.

Decoy selects peptide conjugate targets based on the following criteria:

- Potential for a therapeutic that can address multiple disease indications with one drug.
- The presence of a natural "starting peptide" that Decoy's platform can rapidly optimize into a promising therapeutic.
- Potential to create a peptide conjugate therapeutic with a novel and differentiated value proposition that meets a significant unmet medical need.

Decoy believes that this target selection strategy will maximize the return on investment from the IMP^{3}ACT platform by allowing Decoy to efficiently advance paradigm creating therapeutics across its peptide conjugate, peptide drug conjugate and peptide-PROTAC molecules.

Decoy's goal is to become a fully integrated biopharmaceutical company with a pipeline of novel therapeutics with targets selected as outlined above. Decoy intends to achieve this goal by pursuing the following strategic objectives:

- **Achieve clinical proof-of-concept for Decoy's platform by bringing its lead *pan-Coronavirus* antiviral forward through a Phase 2 human challenge clinical trial.** Even though COVID-19 has largely moved into an endemic phase, Decoy believes there is still a significant global unmet medical need among immune-suppressed people that this program can fill, giving it meaningful economic value. To date, this program has been largely supported by non-dilutive funds and this funding source continues to be the mechanism through which Decoy is validating many of the technologies in its platform. Decoy believes it will continue to attract such funds to advance this program in the clinic.
- **Bring forward 1 additional transformative program to IND-enabling status within two years.** Decoy aims to leverage the speed and efficiency of its peptide conjugate design and development platform to bring forward additional potentially transformative peptide conjugate therapeutics that meet the target selection criteria outlined above to the IND-enabling stage of development with 24 months. Decoy expects that this program could have the potential to deliver a novel value proposition that is not currently available to patients and healthcare providers.
- **Thorough review of SP-2577 to drive a decision on whether to continue development internally or position this asset for out-licensing.**
- **Build a platform manufacturing capability:** Decoy intends to pursue platform manufacturing designation from the FDA, allowing it to rapidly scale-up the manufacturing of novel peptide-conjugate drug candidates for pre-clinical and clinical studies in a repeatable and cost-effective manner. Decoy believes this would significantly enhance its ability to quickly advance novel and economically valuable therapeutic programs.
- **Continue to access non-dilutive funding.** To date, Decoy has been able to attract significant non-dilutive funding to support its programs and platform from organizations such as The Bill & Melinda Gates Foundation (BMGF), BARDA, Google, and the IMI-Care Consortium. Decoy expects to continue seeking such funds in the future.
- **Pursue value-enhancing partnerships.** Decoy believes it can rapidly create and validate novel therapeutic assets. Consequently, Decoy aims to attract capital and relevant capabilities in later-stage development and commercialization to these programs by selectively seeking partnerships for these assets that Decoy believes will be value enhancing to its company.
- **Maintain Pandemic Readiness: Preserve the Pandemic "Call-Option" Embedded with the IMPACT Platform.** Based on Decoy's goals, Decoy's platform is well-positioned to rapidly advance antiviral therapeutics in response to the emergence of novel and dangerous viral pathogens, especially in several of the viral families that are often considered to be the most likely sources of such a pathogen, for example, avian influenza. Decoy will continue to actively work with governmental agencies and non-governmental

organizations globally to provide funding to further develop peptide drug conjugates against developing global threats. Given the financial returns to their sponsors from therapeutic assets such as the mRNA vaccines and Paxlovid during the COVID-19 pandemic, Decoy considers this capability to be a valuable 'call option' on the next epidemic or pandemic.

Decoy's Management and Management of the Proposed Combined Company

Decoy's management, co-founders and scientific advisor board include highly experienced senior scientists, clinicians, biotechnology and pharmaceutical executives, and a renowned professor of peptide chemistry from the Massachusetts Institute of Technology ("MIT"):

- Rick Pierce, Chief Executive Officer and Director, a serial biotech entrepreneur who has helped build a number of biotechnology companies over the last 25 years, including Javelin Pharmaceuticals, which was sold to Pfizer, which now markets its lead drug, Dyloject.
- Barbara Hibner Ph.D., Chief Scientific Officer and Director, with over 25 years of experience in pharmacology and drug discovery and development in pharmaceutical and biotechnology companies resulting in contributions to 2 oncology drugs sorafenib and ixazomib.
- Peter Marschel, MS MBA, Chief Business Officer & Director with over fifteen years of experience in business development, financial and commercial roles at large pharmaceutical and biotechnology companies, including leading market analytics for the cystic fibrosis franchise at Vertex Pharmaceuticals.
- Michael Lipp, Ph.D. Chief Technology Officer with over two decades of experience in pharmaceutical development and drug delivery technologies ranging from the preclinical stage through commercial approval.
- Bradley L. Pentelute, Ph.D., Professor of Chemistry at MIT and co-founder, whose lab invented the world's fastest peptide synthesizer and has advised large pharmaceutical and biotechnology companies on advancing their peptide drug discovery and manufacturing efforts.
- Shahin Gharakhanian, MD, SAB chair and acting-Chief Medical Officer, is a Physician-Executive with expertise in pharmaceutical medicine, leadership and management, and an international track record and former Vice President within the Medicines Development Group, Global R&D at Vertex Pharmaceuticals with 2 antiviral drugs taken successfully to commercialization.

In addition, Mark Rosenblum, Executive Vice President and Chief Financial Officer of Salarius, is expected to serve as Chief Financial Officer of the combined company.

Decoy currently has eight full time employees and seven consultants, responsible for preclinical, toxicology, clinical development, prescriber, payor, market access and pricing strategy, chemistry manufacturing and controls (" CMC"), quality, and regulatory strategy and execution, finance strategy and business development.

Decoy's Scientific Advisory Board

Decoy also has four members of its Scientific Advisory Board chaired by Dr. Shahin Gharakhanian:

- Dr. Shahin Gharakhanian, SAB chair.
- Dr. Mark Garnick is an internationally renowned expert in medical oncology and urologic cancer and has served for 15 years as a member of an FDA Oncologic Drug Advisory Committee. A clinical professor of medicine at Harvard Medical School, he also maintains an active clinical practice at Beth Israel Deaconess Medical Center.
- Dr. Daniel Kuritzkes, Chief of Infectious Disease at Brigham and Women's Hospital and professor of medicine at Harvard Medical School; and

- Yonatan Grad, epidemiologist and professor of immunology and infectious disease at Harvard T.H. Chan School of Public Health.

Decoy's employees and advisors have significant industry experience and have been involved in the discovery, development, regulatory approvals, and commercial launches of several successful drugs.

Financing Model

Decoy's financing model has historically consisted of partnerships with industry entities, domestic and foreign government agencies, and non-governmental organization funding. This approach has been highly efficient and allowed Decoy to operate with relatively low annual cash burn rate and dilution compared to many of its peers.

Decoy has garnered substantial non-dilutive funding, support, and ML/AI computation credits equal to or greater than what Decoy has raised from institutional investors. Decoy has received significant grants from The Bill and Melinda Gates Foundation and the U.S. government's Blue Knight Program, and support from the European Union's IMI-CARE Consortium, the Canadian government's National Research Council, GOOGLE's AI Startup Program, and NVIDIA's Inception Program.

Market Opportunity for Decoy's Current Drug Development Programs

Decoy sees opportunities in each of the four main areas of its drug discovery program efforts:

COV: Pan-Coronavirus Inhibitor for Immunocompromised Patients

According to the most recent December 2024 World Health Organization publication on COVID-19, while there are periodic waves of COVID-19 in some countries, SARS-CoV-2, the virus that causes COVID-19, largely circulates without clear seasonality, and continues to infect, cause severe acute disease and post COVID-19 condition (long COVID).[1] Currently, the primary tools to combat the virus involve mRNA vaccines and medications like Paxlovid, which are effective at avoiding severe outcomes in patients at high risk for progression to severe COVID-19. However, Paxlovid cannot be used prophylactically, either before or after exposure and has a significant Drug-Drug Interaction[2] ("DDI") profile, leaving a large treatment gap and negative outcomes for patients who are immune-suppressed or who have high-risk comorbidities and do not respond significantly to vaccines. Early in the pandemic, long-acting antibody-based prophylactics like Evusheld were prescribed for immune-suppressed patients. These antibody therapeutics quickly became obsolete due to the rapid and continued evolution of the SARS-CoV-2 virus. More recently the antibody Pemgarda was approved under an emergency use authorization for pre-exposure prophylaxis of COVID-19 in certain high-risk individuals. As with other antibodies, Pemgarda is at risk of losing efficacy as the virus continues to mutate; the most recent SARS-CoV-2 viral variants have ~ 150 mutations compared to the original viral sample, with no indication that viral evolution is slowing.

Decoy commissioned market research in 2022[3] that indicated important medical unmet needs in the treatment and prevention of COVID-19, including:

- **Prophylaxis for current and future variants in high-risk patients**: Health care providers, or HCPs, are concerned about preventing and minimizing severe cases in patients at risk. This is considered particularly critical if or when new variants arise.
- **Easy-to-use route of administration**: Key opinion leaders noted the need for non-injectable preventative products to enable broad availability by reducing infrastructure requirements. This type of treatment also avoids the need for high-risk patients to visit healthcare facilities for administration.
- **Effective treatments with better DDI profile**: DDIs, such as those seen with Paxlovid, are a concern for HCPs, especially when considering that high risk patients tend to have other comorbidities and are most probably already on other treatments.

[1] https://www.who.int/publications/m/item/covid-19-epidemiological-update---24-december-2024
[2] https://paxlovid.pfizerpro.com/drug-interactions
[3] Primary market research performed by Bionest Partners in Oct/Nov 2022: 13 HCPs, 13 Payers in US, DE, FR, IT,UK.

This market research, which included both HCP and payer studies across the United States and the European Union, indicated that there are 20 million or more patients in the United States and Europe that many HCPs consider to be at 'highest risk' from COVID-19 and other respiratory viral infections, and a favorable outlook for reimbursement for therapeutics that can fill treatment gaps for these patients.

Decoy's lead program is a broad-acting antiviral nasal spray to prevent or mitigate COVID-19 infections in high-risk, immunocompromised populations for whom there are limited treatment options. This agent has been shown to be active in vitro against all human infecting Coronaviruses, including all COVID-19 variants that have emerged to date, would be conveniently self-administered, and is expected to provide 8-24 hours of antiviral activity. Decoy also believes that it will be able to manufacture this nasal spray with a low cost of goods.

Decoy expects multiple potential attractive development and commercialization options for an inhaled pan-Coronavirus fusion inhibitor, including:

- Pre- and post-exposure prophylaxis ("PrEP"/"PEP") for highly immunocompromised populations that face elevated risks due to severe immune deficiencies associated with conditions such as hematological malignancies and immunosuppressive medical treatments in the context of hematopoietic stem cell transplantation and solid organ transplants, with the potential for label expansion to other immunocompromised and at high-risk populations. The market research mentioned above suggests there may be over 5 million such patients in the United States and EU, and that an estimated net price of up to $500 per 30-day supply in the United States is feasible.

- Post-infection treatment as an alternative to Paxlovid, with a superior DDI profile. Morningstar research projects full year 2024 revenues exceeding $5 billion[4] for Pfizer's Paxlovid, despite Paxlovid's notable DDIs with widely prescribed drugs such as statins (prescribed to over 90 million Americans) and calcium channel blockers (prescribed to more than 20 million Americans), which underscore the critical need for a safer alternative. Many of these patients have serious pre-existing conditions that put them at significant risk from COVID-19 infection, but there have been emerging concerns that Paxlovid is under-prescribed to high-risk patients because of DDI concerns. As of October 18, 2023, Paxlovid's list price in the United States was $1,390 for a 5-day course[5].

Decoy also believes there may be additional opportunities for a pan-Coronavirus fusion inhibitor to generate revenue from public health authority stockpiling of drug for pandemic preparedness and military readiness purposes.

Decoy's plan is to initially develop this agent as a pre- and post-exposure prophylactic for a targeted subset of the immunocompromised, such as patients with hematological malignancies and post-transplant patients, that have both a very high unmet medical need and can be accessed in the United States by a small, specialized sales force focusing on a small number of cancer treatment and transplant centers. Decoy then plans to expand from there to additional indications, including potentially novel dose regimens and inhalation routes optimized to new indications.

Decoy recognizes the rapid evolution of the COVID landscape and will continue to strive to conduct key opinion leader, health care provider, payer, and patient market research and potentially adjust its plans based on those findings.

TRI: Broad Respiratory Antiviral (Flu/COVID/RSV)

Decoy is engineering a groundbreaking approach to combat Flu/COVID/respiratory syncytial virus (RSV) infections with a single peptide conjugate antiviral that is potentially effective against all three major respiratory viruses, including activity against pandemic flu strains if possible.

By addressing the tripledemic with a single therapy, Decoy aims to revolutionize the management and treatment of respiratory illnesses caused by these viruses. Respiratory tract infections represent an important unmet medical need, exerting a significant toll on patients and public health systems worldwide. The seasonal convergence of influenza, RSV, and COVID-19, often referred to as the "tripledemic," has intensified the burden of these infections,

[4] https://www.morningstar.com/news/business-wire/20241029363831/pfizer-reports-strong-third-quarter-2024-results-and-raises-2024-guidance
[5] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-price-covid-19-drug-paxlovid-1400-five-daycourse-wsj-2023-10-18/

which are often vectors to dangerous and expensive lower respiratory infections. Despite the availability of vaccines targeting these viruses, and with decreasing vaccine uptake, hospitalizations, ICU admissions, and fatalities attributed to respiratory viruses continue to strain healthcare resources underscoring the need for effective therapeutic interventions.

Decoy's single therapy approach potentially offers several key advantages:

- A single therapy with proven efficacy against all three viruses could potentially eliminate the need for multiple treatments, streamlining patient care and reducing complexity for healthcare providers.
- Decoy's therapy is expected to be self-administered, offering convenience and autonomy to patients.
- Peptide conjugates to date have a favorable safety and tolerability profile.

Given the ease of use and safety of the envisioned product profile, Decoy intends to work towards a commercialization approach that will make this product, if approved, broadly accessible to symptomatic patients, leveraging emerging channels such as telehealth, digital patient engagement and at-home delivery.

In the United States, the combined impact of influenza, RSV, and COVID-19 results in an estimated 15 to 20 million medical visits annually among patients aged 18 and older. This significant healthcare utilization underscores the burden of respiratory tract infections on the healthcare system.

Expanding the market to include individuals with symptomatic illness who may not physically visit a doctor's office approximately doubles the number of eligible adult patients. With the increasing adoption of telehealth services and the advancement of wearables signaling very early respiratory infections, there is a tangible opportunity to expand the market for respiratory tract infection treatments beyond patients who traditionally seek in-person medical care.

Given these factors, Decoy believes its 'tripledemic' antiviral program could represent the cornerstone of a significant global franchise.

cGPCR: GPCR-Targeted Conjugate for CRC/GI Tumors

Decoy aims to investigate an under-utilized cell membrane molecule class, GPCRs, as oncology precision medicine targets.

Decoy's IMP^{3}ACT peptide discovery platform optimizes natural GPCR α-helical peptide ligands for improved drug properties. Decoy's Design-Build-Test-Learn Cycle integrates AI-driven and physics-based design, rapid peptide synthesis, and experimental testing. This iterative process builds a proprietary database, potentially enhancing Decoy's AI's predictive capabilities for GPCR peptide ligands.

The identification of one or more novel colon tumor overexpressed GPCR biomarkers and the subsequent design and synthesis of an engineered peptide ligand has the potential to create a new paradigm for personalized medicine for colon cancer. GPCR-based novel peptide drug conjugates or radionuclide therapies can transform cancer treatment with high therapeutic window medicines so desperately needed for drug resistant and metastatic colon cancer patients.

Colon cancer therapies have changed little over the last decades, with mainstay therapies continuing to revolve around Fluorouracil ("5-FU"), platinum, and irinotecan combinations, typically with the addition of an anti-VEGF treatment. Only a small percentage of colon cancer patients have a biomarker that allows the incorporation of a 'precision medicine' where characteristics of the patient tumor drive selection of a specific therapy (for example, the 3-5% of CRC patients with amplified HER2 become eligible for the ADC trastuzumab deruxtecan). There is a high need for the identification of new cell membrane and internal protein targets to create multiple options for precision treatments for the majority of colon cancer patients, including late stage metastatic and drug resistant tumors.

According to the most recent American Cancer Society (the "ACS") report released in January 2024, is the ACS estimated 152,810 new cases of colorectal cancer diagnosed in the United States in 2024, with approximately

20% of these diagnosed at a late stage. The incidence rate of colorectal cancer continues to rise between 1% and 2% each year in people under the age of 55, an alarming trend since the mid-1990s.[6] The mortality rate in young people is also increasing about 1% each year since the mid-2000s. Colorectal cancer has now become the leading cause of cancer death in men under 50 and the second leading cause in women of the same age group. Young people are often diagnosed with more advanced cancers due to delays in detection. Overall, CRC is the second leading cause of all cancer-related deaths in the U.S., with an estimated 53,010 deaths in 2024.

GPCRs have a high potential to target peptide drug conjugates or peptide receptor radionuclide therapy (PRRT), as exemplified by multiple approvals of somatostatin theranostics to diagnose and treat GI neuroendocrine tumors.[7] The structure of GPCRs is well conserved, with a defined architecture, and the ligand binding sites are on the outer cell membrane. Over 100 GPCRs have endogenous peptide ligands, and many GPCR peptides display a regular a-helical structure in solution[8], a structure that provides an excellent natural starting point for Decoy's innovative IMP^{3}ACT design platform. While not classic driver mutations, several GPCRs with natural a-helical peptide ligands have been reported to be overexpressed in colon tumors compared to normal tissue, in some cases in resistant and metastatic tumors.[9] Typically, antagonists of GPCRs will lead to internalization, necessary for peptide drug conjugates to deliver a payload inside the cell. Decoy hypothesizes that by using state of the art AI tool- boosted immunohistochemistry to quantify GPCR cell membrane expression at the protein level, Decoy may identify one or more new colon tumor biomarkers suitable for further exploration in PDC or PRRT therapies.

Decoy's IMP^{3}ACT Platform

Overview of Peptides and Peptide Conjugate Therapeutics

A key proposed advantage of the peptide-conjugate modality as exemplified by product candidates engineered and synthesized by Decoy's IMP^{3}ACT Platform is the opportunity for 'polypharmacology', in which a single molecule can activate or inhibit multiple targets/receptors in an additive or synergistic manner to achieve superior or multi-indication efficacy.

The success of multi-targeting peptide conjugates is due to careful peptide design based on the structural similarity between the two GPCRs or viruses and is an exciting advantage of peptide-conjugates that is difficult to match with other therapeutic modalities, and contrasts with the often unpredictable off-target effects of small molecules.

An FDA approved example of polypharmacology is the newest obesity drug, Eli Lilly's blockbuster ZepBound™, in which a single peptide conjugate demonstrates agonism of two different GPCRs: glucagon-like peptide 1 receptor (GLP-1R), and gastric inhibitory peptide receptor. A second example is Decoy's lead program, a peptide-conjugate antiviral therapeutic, that has demonstrated activity against multiple related viral pathogens.

Peptides are short chains of amino acids linked together by peptide (amide) bonds, typically less than 50 amino acids long, which play a vital role in a wide range of biological processes. Secondary atomic interactions between amino acids cause peptides to fold into complex 3-dimensional structures, one of the most common of which is an α-helical coil. α-helical peptides and proteins are ubiquitous in human biology, and α-helices often interact chemically with other α-helices driving protein-protein and protein-nucleic acid interactions, so peptides with α-helical structures can often be the basis for effective therapeutics.

Peptides have important innate advantages when compared to small molecules and antibody-based therapeutics[10]:

- **High potency and specificity:** Peptides bind a larger surface area of the target than small molecules, and therefore are highly selective with very tight binding.

[6] https://colorectalcancer.org/article/acs-releases-colorectal-cancer-estimates-2024
[7] Susini, C. & Buscail, L. Rationale for the use of somatostatin analogs as antitumor agents. Ann. Oncol. 17: 1733-1742 (2006).
[8] Kaiser, A and Irene Coin. Capturing Peptide-GPCR Interactions and Their Dynamics. Molecules 25, 4724 (2020).
[9] Insel, PA et. al. GPCRomics: GPCR Expression in Cancer Cells and Tumors Identifies New, Potential Biomarkers and Therapeutic Targets. Front Pharmacol. 9:431 (2018).
[10] PLoS ONE 17(3): e0255753. https://doi.org/10.1371/journal. pone.0255753

- **Excellent safety profile with predictable metabolism:** Because they easily diffuse across cell membranes small molecules often have off target toxicities that can limit or nullify their therapeutic potential. Peptides typically do not passively diffuse, and they are usually readily metabolized into non-toxic compounds.
- **High tissue penetration versus. antibodies:** Antibody-based therapeutics are very large molecules (~30x the size of peptides) and thus have difficulty diffusing deep into tissues from blood vessels.
- **Simpler manufacturing, lower cost of goods:** Peptides are manufactured using synthetic chemistry, whereas antibody-based therapeutics require complex and intensively regulated biological processes.

Small peptides as drugs, however, have an intrinsic limitation; they are subject to rapid enzymatic digestion and clearance from the GI tract or in the bloodstream, limiting their half-life and oral bioavailability.

Peptide conjugates solve this problem by chemically linking a peptide, typically via a polyethylene glycol (PEG) structure, to one or more additional molecules, often another biological molecule such as another peptide, nucleic acid, or a fatty acid, which enhance the drug-like properties of the conjugate by improving enzymatic stability, half-life in the bloodstream or at the target, and bioavailability, while also maintaining low immunogenicity.

The IMP^{3}ACT Platform

The Immediate Peptide/PPMO/P-PROTAC Alpha-helical Conjugate Technology ("IMP^{3}ACT") platform leverages peptide 'coiled-coils' chemistry and physics to design α-helical peptides through computational and ML tools. Starting from naturally existing peptide ligands, Decoy optimizes their structure and transform them into multimeric conjugates by chemically linking multiple copies to lipids and other suitable anchor moieties, enhancing their drug-like properties and dosing flexibility with extended pharmacokinetics. Notably, Decoy's technology has produced single peptide conjugates that are active against multiple human coronaviruses, including all the SARS-CoV-2 major variants of concern to date, and a second conjugate that is active against RSV A, RSV B, and hPIV3. By integrating ML algorithms in peptide design and synthesis, Decoy's platform accelerates the creation of lead molecules for preclinical evaluations, simultaneously optimizing peptide conjugates for enhanced affinity, binding specificity, resistance to proteases, pharmacokinetic properties, and manufacturability at early commercial scale.

The efficiency of Decoy's IMP^{3}ACT platform may enable Decoy to achieve peptide conjugate manufacturing readiness faster than conventional drug development processes, leading to reduced manufacturing costs and accelerated delivery of broad-spectrum drug candidates to IND. The modular nature of these drugs and processes also means that each new drug candidate improves the overall platform, and the likelihood of success should grow as the experience base teaches the ML/AI models. By employing solid phase peptide synthesis in an "All-in-One" manufacturing approach, Decoy optimizes the assembly of complex peptide-linker-functionalized compounds, enhancing the speed, efficiency, and predictive value of the IMP^{3}ACT platform.

The Design-Build-Test-Learn Engine

Decoy has integrated advancements in data science, peptide conjugate chemistry, and manufacturing processes, underpinned by strong foundational research, to create its IMP^{3}ACT platform. The core of this innovation is the Design-Build-Test-Learn Cycle: the "Design" component utilizes AI *in silico* approaches to analyze existing protein and genomics datasets and make structure-function predictions, the "Build" cycle component implements fast flow synthesizers that can generate peptide candidates faster than industry standard synthetic practices, and the "Test" cycle incorporates experimental testing of peptide physiochemical properties and activity via reliable assays to characterize peptide-candidates. The learn cycle capitalizes on the experimental data to redesign new and improved *in silico* candidates.

This integrated, multiparameter approach is designed to streamline the drug discovery process, making it faster, more efficient and with greater attention to drug-like and commercialization properties. Additionally, Decoy believes that continuing to iterate on its Design-Build-Test-Learn loop will generate valuable proprietary data that can drive its *in-silico* models to generate design solutions that would otherwise not be available from computational approaches. Decoy's hypothesis is that the key to value-creation in ML/AI driven drug design is well-structured,

useful, and proprietary data and the knowledge on which tools to use when, not on the computational models themselves. Decoy's platform strategy will help Decoy become the leaders in designing and developing a--helical peptide-conjugate therapeutics in its chosen target areas.

Figure 1: The major components of Decoy's Design-Build-Test-Learn iterative loop.

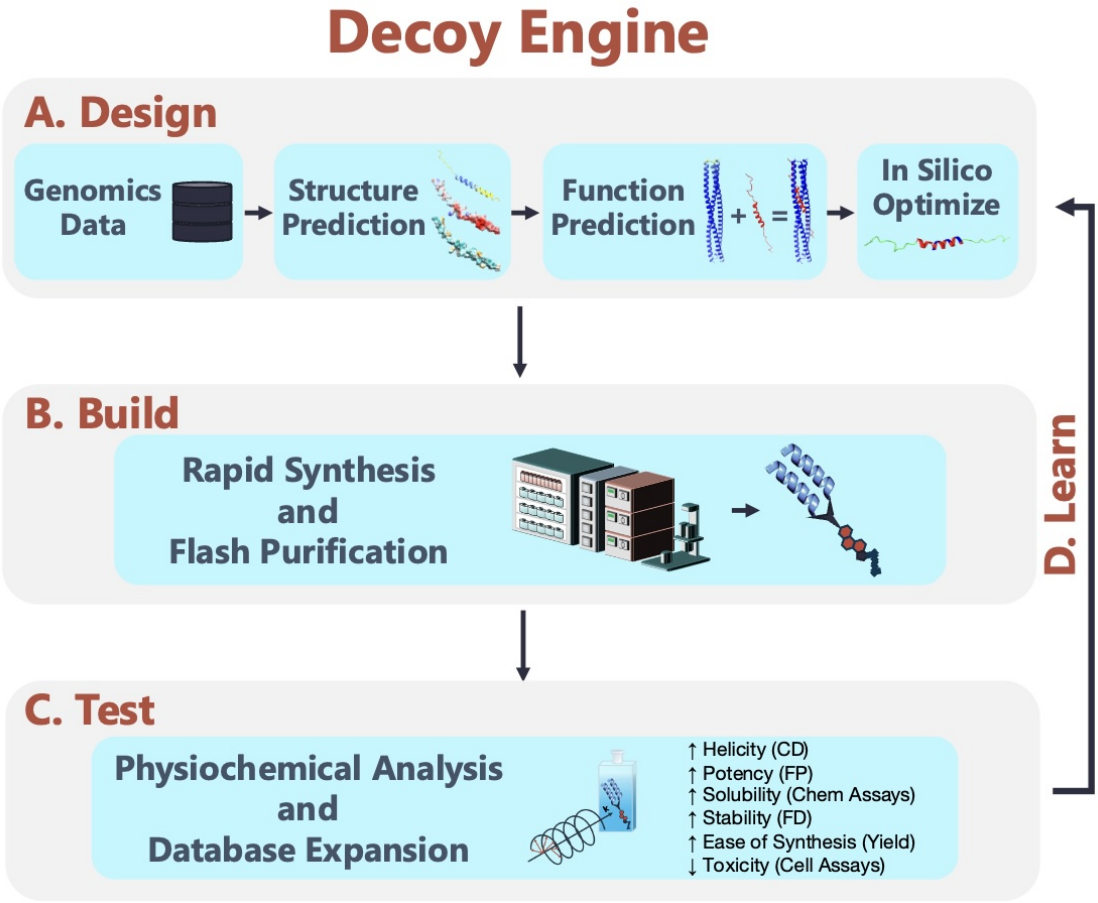


Figure 1. Flow schematic of Decoy's engine for rapid drug discovery. (A) The design stage capitalizes on metagenomics data to create structure-function predictions and further optimize peptide ligand sequences based on *in silico* readouts. (B) Decoy's build stage uses fast flow synthesis to create select candidates that pass *in silico* criteria. (C) At the test stage, biophysical assays check peptide candidates for a variety of readouts. (D) Through the learn stage, experimental data is used to guide new and improved *in silico* designs.

Starting from Existing Peptide Ligands

A key element of Decoy's platform strategy is to start from naturally existing peptides, leveraging 'nature's starting points' to improve drug development program timelines and risk. Typically, Decoy can rapidly synthesize a peptide conjugate that incorporates a naturally existing peptide sequence, and which is immediately active against the target in question. Decoy believes this is an excellent starting point for the Design-Build-Test-Learn loop because it significantly decreases the size of the peptide conjugate design space, making it computationally tractable to immediately begin optimizing for drug-like properties.

Additionally, Decoy's *in-silico* engine uses ML, AI, and physics-based computational tools to identify helical motifs within metagenomics data that are shared across targets. This enables Decoy, especially when starting from existing peptide ligands, to rapidly design polypharmacologic peptide conjugates in which one drug can potentially interact with multiple targets, unlocking the potential for very broad activity across several indications from a single peptide conjugate. For example, these ML-driven a-helical drug candidates have the potential to inhibit a wide range of viruses by targeting the viral fusion machinery, a critical component utilized by enveloped viruses for viral entry and subsequent replication in the host cells. Similarly, Decoy will leverage the virally trained a-helical database to train the engine to target one or more GPCRs with innovatively designed a-helical ligand agonists or antagonists.

Multiparameter Optimization of Drug Properties

The IMP^{3}ACT Platform acts as an iterative feedback loop and incorporates data from multiple *in vitro* experiments to improve the design parameters of the candidate peptides. The real power of this approach lies in optimizing against multiple parameters at the same time. In the past, the drug-development industry has typically relied on 'one step at a time' optimization that often leads to a highly restricted chemical design space in which important downstream attributes, like pharmacokinetic behavior, cannot easily be enhanced. By using all the experimental data relevant to *making a drug* to train the ML engine as computational guides, more drug-like peptide conjugates with optimized functionality against one or more targets and with optimized commercialization potential (pharmacology, formulation, manufacturability) may be designed. This multiparameter optimization approach not only reduces the costs associated with combinatorial research investigations but will also significantly decrease the probability of pre-clinical or clinical failures by avoiding 'dead end' development paths.

Rapid synthesis

Decoy is using a fast-flow automated process coupled with a proprietary "All-in-One" method (patent pending) to synthesize multiple peptide-conjugates on lab-based machines. The yield (5-100 mg depending on desired scale) and purity is sufficient for conducting multiple *in vitro* tests including physicochemical properties and biological function. This innovation dramatically decreases the cycle time to learn the structure-activity relationships for different peptide designs and enables Decoy's construction of a multiparameter structure-activity-drug-like proprietary database on a-helical peptides.

Compared to standard industrial solid phase synthesis, fast flow synthesis leverages the use of a heated reactor to accelerate synthetic speed, allowing amide bond formation creation in just 7 seconds per amino acid, compared to around 1 hour per cycle in traditional methods. In addition, fast flow synthesis can be automated to eliminate human intervention and errors, and work in a high throughput fashion. Mijalis et al tested the speed of synthesis of a growth-homone-releasing hormone peptide hormone, showing that the fast flow machines can generate the peptide 45 times faster than standard batch synthesis, in 40 minutes versus 30 hours[11]. The crude peptide output and yields are better than standard batch synthesis. This automated approach enables rapid peptide conjugate production while maintaining high quality, making it suitable for applications like drug discovery that require synthesizing multiple peptide conjugates rapidly, thus shortening the overall time to optimize a clinical drug candidate.

By innovative design, Decoy has invented a multi-arm linker which is compatible with solid phase peptide synthesis methods and can be used to build complex biomacromolecules containing branched peptides and other functionalities in one synthetic run. These complex molecules can be differentially functionalized in such a way so that non-peptide functionality can be attached to them while the whole molecule is still attached to the solid phase resin; Decoy's proprietary "All-In-One" manufacturing. When the desired molecule has been built, the intact, desired compound can be cleaved from the resin, purified by suitable means, and isolated for formulation and administration.

Using fast-flow synthesis technology coupled with the above process, the research scale synthesis of a peptide conjugate is reduced from several months, typical at a standard CDMO, to days or even hours. Decoy's IMP^{3}ACT platform is a unique lead optimization engine that can rapidly design from natural peptide ligands and identify optimized drug-like lead molecules. Additionally, Decoy is currently evaluating the use of its "All-In-One" process

[11] Mijalis AJ, et. al. A fully automated flow-based approach for accelerated peptide synthesis. Nat Chem Biol. 13(5):464-466 (2017).

at commercial scale, which would enable further time savings in the transition from preclinical to good laboratory practices and current good manufacturing practices scale up.

Testing

Decoy is focused on using *in silico* and empirical assays that have predictive value. In the design engine the *in-silico* tools have been validated against the actual data (e.g., binding affinity, solubility, protease resistance, manufacturability etc.) to ensure reliability of the computational predictions. The screening cascade for each program will rely on predictive assays to streamline the work and decision making. Where possible, human organoid and epithelial tissue models are incorporated to improve predictive power, as rodent efficacy models have moderate predictive value and it can be difficult to translate the pharmacokinetics to human tissues, especially for local peptide conjugate exposure in the nose or lungs as needed for an intranasal or inhaled program. Rodent noses are substantially different to human, and it is difficult to control compound delivery and tissue analysis in intranasal and inhaled studies. Organoid models are also significantly less expensive, and easier to scale-up, than animal models.

The human airway epithelial ("HAE") model is a cell culture system that is grown at an air-liquid interface ("ALI"). This *in vitro* culture system is designed to mimic the conditions of the human airway epithelium more closely than traditional submerged cell cultures. In the ALI setup, the basal surface of the human airway (nasal, bronchial, or alveolar) cells is in contact with a liquid culture medium, while the apical surface is exposed to air. This configuration promotes the differentiation of the cells into a mucociliary phenotype, which is characteristic of the pseudostratified epithelium found in the human respiratory tract, including the presence of ciliated and mucus-secreting cells. The ALI culture system is physiologically relevant and is used for various research applications, including studying the cell biology of the respiratory epithelium, modeling respiratory diseases, studying respiratory epithelium infections and effects of drugs on the respiratory epithelium.

SARS-CoV-2 HAE-ALI experiments have demonstrated that this model recapitulates human data: SARS-CoV-2 infection kinetics have been studied, and the peak of viremia occurs between days 4 and 8 in HAE-ALI culture. Human SARS-CoV-2 viral kinetics peak in the nasal epithelium between days 4 and 8 as delineated in a human challenge trial.[12] Additionally, multiple coronaviruses have been tested in the HAE-ALI culture and their growth kinetics and cellular effects correlate to human experience across the seasonal ('cold-causing') versus pandemic viruses. Both influenza and RSV have been modeled in HAE and used to test the infectivity of new strains as well as therapeutic efficacy.

Beyond use in respiratory viruses, human organoid models are gaining widespread acceptance as a predictive tool for cancer drug development. Recently, an analysis of drug responses in patients and in their matched cancer organoids led to the conclusion that responses to the drugs are highly similar in the two settings. A drug with no antitumor activity in the tumor organoids did not demonstrate efficacy in the matched patient, and drugs that showed an effect in the organoid cultures were matched by a patient response in close to 90% of cases. This study has been corroborated by several studies with larger cohorts. Human organoids may be highly predictive in vitro models for candidate drug screening that could improve the clinical success rate for a variety of therapeutics.

Additional pre-clinical work will include quantitative pharmacology and model- based approaches in conjunction with toxicology information in both human model systems and animal studies to project the human starting dose for phase 1 studies with appropriate modeling consideration for any delivery device.

Scale-Up Manufacturing

Decoy is working internally as well as in collaboration with multiple Contract Manufacturing Organizations ("CMOs") to develop and scale-up proprietary and GMP-compatible manufacturing processes to produce peptide conjugates generated from its IMP^{3}ACT platform. As described earlier above, the efficiency of Decoy's IMP^{3}ACT platform enables Decoy to achieve peptide conjugate manufacturing readiness faster than conventional drug development processes, leading to reduced manufacturing costs and accelerated delivery of broad-spectrum drug candidates.

[12] Lindeboom, R.G.H., Worlock, K.B., Dratva, L.M. et al. Human SARS-CoV-2 challenge uncovers local and systemic response dynamics. Nature 631, 189-198 (2024). https://doi.org/10.1038/s41586-024-07575-x

By employing solid phase peptide synthesis in an "All-in-One" manufacturing approach, Decoy optimizes the assembly of complex peptide-linker-functionalized compounds, enhancing the speed, efficiency, and predictive value of the IMP^{3}ACT platform. Decoy is currently working with a major peptide manufacturer to scale the "All-in-One" manufacturing process to quantities useful for pre-clinical development potentially through early-stage clinical trials at minimum; Decoy anticipates new intellectual property will be an outcome of this collaboration. Decoy's goal is pre-clinical manufacturing readiness within significantly shorter timelines compared to traditional drug development processes, aiming to eventually meet or exceed the100-day goal for vaccine manufacturing; in other words, moving from an initial natural peptide ligand to drug lead in a single quarter.

Formulation Flexibility

Traditionally peptides as drugs have suffered from very low bioavailability, limiting their delivery to intravenous or subcutaneous routes. Decoy is exploring multiple routes of administration, with an emphasis on self-administered methods including:

- Intranasal, including nose-to-brain delivery.
- Inhaled/pulmonary delivery (local and systemic applications)
- Subcutaneous patches for extended systemic release.
- Oral.

Decoy is engineering its peptide conjugates to possess the required physicochemical and pharmaceutical properties to enable each of these routes of delivery, including solubility, chemical stability, resistance to proteolytic degradation and compatibility with a range of pharmaceutically acceptable excipients. Results to date indicate that Decoy's peptide conjugates can be formulated into both liquid and dry powder-based dosage forms that are room temperature stable and suitable for administration via a range of delivery devices such as liquid and dry powder-based nasal and pulmonary inhalation devices and syringes.

Competitive Strengths of the IMP^{3}ACT Platform

Decoy believes the IMP^{3}ACT platform has several key advantages compared to other drug-discovery approaches:

- **Proprietary Data:** Continuing to run Decoy's Design-Build-Test-Learn loop results in an expanding proprietary data set that should give the IMP^{3}ACT platform a differentiated and difficult to duplicate capability to design novel and promising therapeutic candidates against α-helical targets, for example as found in viruses and GPCRs.
- **Faster & Lower Cost Discovery:** Decoy's ML/AI engine is applying computational tools to model structures, energy costs, binding affinities and specificity, protease resistance and manufacturability to design lead quality molecules in a fraction of the time, and by making significantly fewer candidate molecules, than required in traditional drug discovery methods.
- **Streamlined & Repeatable Manufacturing:** Decoy is currently working to scale-up the "All-in-one" manufacturing process such that it will repeatably utilize the same CMC processes for each new drug candidate Decoy brings forward. Given this, Decoy has applied for the FDA Emerging Technology program based on the Food and Drug Omnibus Reform Act of 2022. Decoy's goal to be able to manufacture 30g of active pharmaceutical ingredient ("API") of a new therapeutic candidate, typically enough material to take a new therapeutic candidate at least through pre-clinical activities, in 30 days.
- **Low Commercial Cost of Goods:** Decoy's manufacturing process is fully chemically synthetic and can be run on standard peptide synthesis machinery, thus avoiding the bioprocess and regulatory complexities of recombinant biological processes. Given this and based on examples from currently marketed peptide conjugate therapeutics, Decoy expects to have very low cost-of-goods-sold (COGS) at commercial scale.

For example, Decoy is aiming for total COGS of less than $1/dose in its lead *pan-Coronavirus* inhibitor program.

- **Flexible Formulation:** Decoy intends to formulate its peptide-conjugate therapeutic candidates in a variety of formats for self-administered routes of administration, including nasal and oral inhalation and extended-release dermal patches. This will allow Decoy to optimize the route of delivery for the indication and market in question.
- **Increased Probability of Success:** Multi-parameter optimization of drug properties from the beginning of the design and discovery process should help Decoy avoid "dead-ends" which can result in expensive and time-consuming drug development failures.

Drug Development Programs

Through Decoy's IMP^{3}ACT platform Decoy aims to create a diverse and expanding development portfolio of antiviral and GPCR-targeted peptide conjugates. Decoy's initial programs are outlined below.

Pan-Coronavirus Prophylactic for Immunocompromised Patients

Decoy is developing this program for the prophylactic prevention of SARS-CoV-2 infection in immunocompromised patients. Decoy has evaluated multiple peptide-conjugate molecules and are currently in late lead optimization stage. This program is supported to IND by grants from the Bill & Melinda Gates Foundation and the Blue Knight Program totaling $6.5 million. It is Decoy's intention to seek additional non-dilutive funding through Phase 2a proof-of-concept (antiviral challenge) studies and a development partner for this program.

The SARS-CoV-2 pandemic demonstrated that vaccines and antiviral therapeutics are complementary tools in the response to viruses. The rapid development of the COVID-19 vaccines saved millions of lives. However, the continued evolution of SARS-CoV-2 immune escape variants, growing 'vaccine hesitancy' among the population at large, and the presence of immune-suppressed sub-groups that are at risk regardless of vaccination status are treatment gaps that can only be filled by antiviral therapeutics.

Decoy's target product profile for this program, developed in conjunction with the Bill & Melinda Gates Foundation, is:

- Prevention of infection by all SARS-CoV-2 variants and other human infecting *coronaviruses* including MERS-CoV
- Convenient self-administration via intranasal spray
- Over 8 hours of protection from a single dose; and
- Cost of goods of less than $1 per dose

Decoy has demonstrated through *in vitro* pseudotype, live virus, HAE assays and *in vivo* Syrian hamster models that multiple Decoy peptide conjugates inhibit viral infection and demonstrate a multifold decrease in viral infectious particles when delivered either before (pre-exposure prophylaxis, or PrEP) or after (post-exposure prophylaxis but before symptoms, or PEP) viral challenge. DCOY101 and its analogs have also demonstrated infection inhibition in cell based assays against all major SARS-CoV-2 variants of concern and other human infecting *coronaviruses*, including SARS-CoV-1, Middle Eastern Respiratory Syndrome, and the "cold-causing" coronaviruses OC43 and NL63, as expected due to the strong similarity of the fusion region structure across *coronaviruses*.

The initial indication for the pan-Coronavirus inhibitor will be PrEP and PEP prevention of COVID-19 in immunocompromised patients. Decoy intends to submit an IND to the FDA within the first half of 2026, and subsequently, if approved, to initiate a Phase I clinical trial in adult healthy volunteers to be followed quickly by a proof-of-concept Phase 2a human "challenge" study in which healthy volunteers are infected with SARS-Cov-2

under controlled conditions[13]. Decoy expects to partner this program after demonstration of human proof-of-concept in the challenge study.

Immunocompromised Populations

The SARS-CoV-2 virus initially infects ciliated cells in the nasopharynx; most people have a mild to moderate illness with viral replication restricted to the upper airways, resolving over 1-2 weeks. In some cases, however, COVID-19 can progress to life-threatening pneumonia with further complications. People that get severe infections often have predispositions, or co-morbidities, including hypertension, heart failure, cardiac arrhythmia, diabetes, kidney failure, chronic pulmonary disease, old age, and/or a compromised immune system. In such cases, infection in the lower respiratory tract can reach the alveoli causing inflammation and limiting gas exchange. Severe illness typically begins 1 week after symptoms start, with shortness of breath and decreased blood oxygen levels, with pneumonia evident as opaque regions on lung X-rays. Patients may meet the definition of ARDS, a form of lung injury with inflammation, pulmonary vascular leakage, and hypoxic respiratory failure. Severe COVID-19 may also lead to disease beyond the respiratory tract, including gastrointestinal, acute cardiac, kidney and liver injury, cardiac arrhythmias, rhabdomyolysis, coagulopathy, and shock. COVID-19 infection can also lead to Long COVID -19, also known as Post COVID Condition ("PCC"), a multisystemic condition that can persist for weeks, months or even years after an infection and vary widely in severity, from mild to debilitating. The risk of contracting Long COVID increases with each time an individual is infected; available data from multiple countries suggests that approximately 6% of symptomatic SARS-CoV-2 infections resulted in PCC despite vaccination[14].

Immunocompromised patients face several distinct challenges:

- Patients post- hematopoietic stem cell transplants or CAR-T therapy are at higher risk of severe COVID-19 within 100 days of treatment, even with rigorous infection control and social avoidance practices.
- Patients with cancer have an impaired immune response to COVID-19 vaccination and are thus at significant risk from SARS-CoV-2 infection.
- Prolonged SARS-CoV-2 infection has been observed in patients with lymphoid or hematological malignancies.
- COVID-19 infections may lead to disruptions of care, for example an interruption in cancer treatment or a delay in a transplant procedure, that can have significant life-altering consequences for patients.

Chronic, persistent SARS-CoV-2 infections in immunocompromised patients are also of public health concern, as the continued evolution of the virus within these patients may be a key source of novel SARS-CoV-2 variants of concern, highlighting an important societal need to prevent infections in this population.

SARS-CoV-2 Burden of Disease Post-Pandemic

SARS-CoV-2 continues to cause significant morbidity and mortality. Between September 2023 and March 2024, approximately 561,000 people were hospitalized in the United States from COVID-19, resulting in approximately 42,000 deaths.[15] By comparison, during the 2023-2024 flu season, a similar timeframe, there were 470,000 influenza-associated hospitalizations and 28,000 deaths. Decoy believes this data strongly suggests that COVID-19 prevalence may be equal to or higher than that of influenza for the foreseeable future.

Current Treatment Landscape and Opportunity

Decoy is not aware of any antiviral that can be used to prevent SARS-CoV-2 infection. There was a recent approval under an emergency use authorization of the prophylactic monoclonal antibody Pemivibart for use in immunocompromised patients, however given the continued evolution of the SARS-CoV-2 virus it is not clear how long this antibody will remain effective.

[13] Nature Medicine (2022) 28:1031-1041.
[14] Wulf Hanson, S. et al. JAMA. (2022) 328(16):1604-1615
[15] https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_weeklyhospitaladmissions100k_00

Therefore, immunocompromised patients, including those facing transplants or cancer treatments, are at particularly high risk of significant morbidity and mortality upon infection with few options. There is a clear unmet medical need for additional safe, novel prophylactic treatments that can act across multiple SARS-CoV-2 variants.

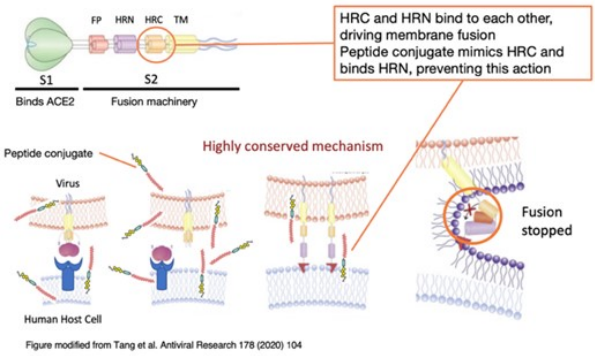
Decoy's Solution – a pan-Coronavirus peptide conjugate fusion inhibitor

Decoy is designing and synthesizing an α-helical peptide simultaneously optimized for multiple features including binding affinity, broad activity against human *coronaviruses*, potency in cell-based antiviral assays, physicochemical features that Decoy understands to be important for pharmacokinetic durability, formulation, and manufacturability. These peptides are linked via a PEG-based linker to a cholesterol molecule. Cholesterol has been demonstrated in scientific literature to significantly improve the pharmacokinetic properties of peptide conjugates.

Mechanism of Action

Viral fusion is required for enveloped viruses to enter human host cells and initiate viral replication. Without fusion, infection will not occur. Treatment with a fusion inhibitor interrupts the infectious cycle of the virus, thus decreasing viral replication. Decoy's pan-Coronavirus peptide conjugates recognize the HRN helical region of the coronavirus spike protein and bind to it (Figure 2). This binding precludes the natural binding of spike HRC to HRN and prevents fusion and viral entry, and thereby decreases viral replication.

Figure 2: Schematic representation of the viral fusion inhibition by a peptide conjugate



Summary of Proof-of-Concept Preclinical Data

In vitro cell based assays:

Decoy has demonstrated that a single Decoy peptide conjugate targeting the fusion machinery can inhibit viral infection for multiple SARS-CoV-2 variants in a pseudotype assay (Wuhan, alpha, beta, gamma, delta, omega BA.1, BA.2,) and in a live virus infection assay (Wuhan, delta, P-1, BA.1, BA.2). Decoy has also shown activity with the same peptide conjugate against 5/6 other human infecting coronaviruses: SARS-CoV-1, MERS, OC43, NL63, and 229E (Fig. 3). The final human infecting coronavirus, HKU1, is difficult to culture in vitro and therefore difficult to test against.

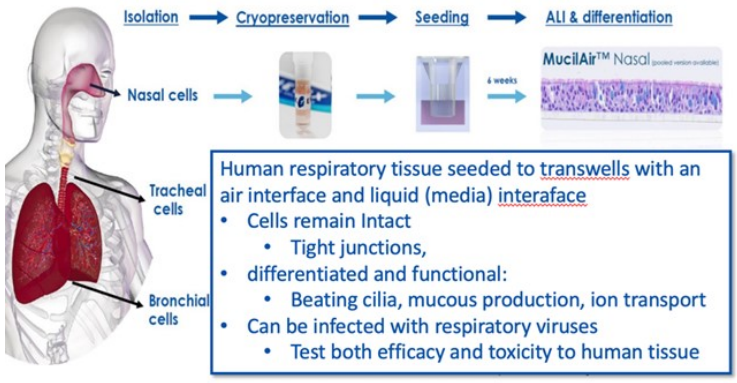
Figure 3: In *Vitro* Antiviral Activity of pan-Coronavirus Peptide Conjugates

		Pseudotype Assay IC50 (μM)			Live Virus Assay IC50 (μM)		
	S2 Hom.	DCOY101	DCOY102	DCOY103	DCOY101	DCOY102	DCOY103
WT (D614G)	100%	0.027	0.027	0.052	0.096	0.184	0.124
Alpha	100%	0.015	0.020	0.033			
Gamma	100%	0.029	0.035	0.087			
Delta	100%	0.020	0.031	0.054	0.035	0.106	0.085
P1	100%				0.025	0.013	0.022
Beta	100%	0.017	0.036	0.103			
BA.1	100%	0.021	0.024	0.042	0.022	0.012	0.019
BA.2	100%	0.017	0.021	0.054			
SARS-CoV-1	100%				0.0009	0.000004	0.00007
MERS	54.9%				0.103	0.468	0.246
OC43	51.6%				0.079	0.035	0.048
NL63	21.9%				0.126	0.367	0.233
229E	26.6%				>1.000	1.29	1.51
Zoonotic Threats	100%	TBD (BatWIV1, BatRs3367, BatRsSCH014, BatCoVZXC21, Bat RaTG13, Pan-CoV-GD)					

Human Airway Epithelial Model:

The HAE-ALI system refers to a HAE cell culture that is grown at an air-liquid interface ("ALI"). This *in vitro* culture system is designed to mimic the conditions of the human airway epithelium more closely than traditional submerged cell cultures. In the ALI setup, the basal surface of the human airway (nasal, bronchial, or alveolar) cells is in contact with a liquid culture medium, while the apical surface is exposed to air (Fig. 4) This configuration supports the differentiation of the cells into a mucociliary phenotype, which is characteristic of the pseudostratified epithelium found in the human respiratory tract, including the presence of ciliated and mucus-secreting cells. The ALI culture system is physiologically relevant and is used for various research applications, including studying the cell biology of the respiratory epithelium, modeling respiratory diseases, studying respiratory epithelium infections and drug efficacy.

Figure 4: Diagram of the Production and Physiological Relevant Features of HAE-ALI

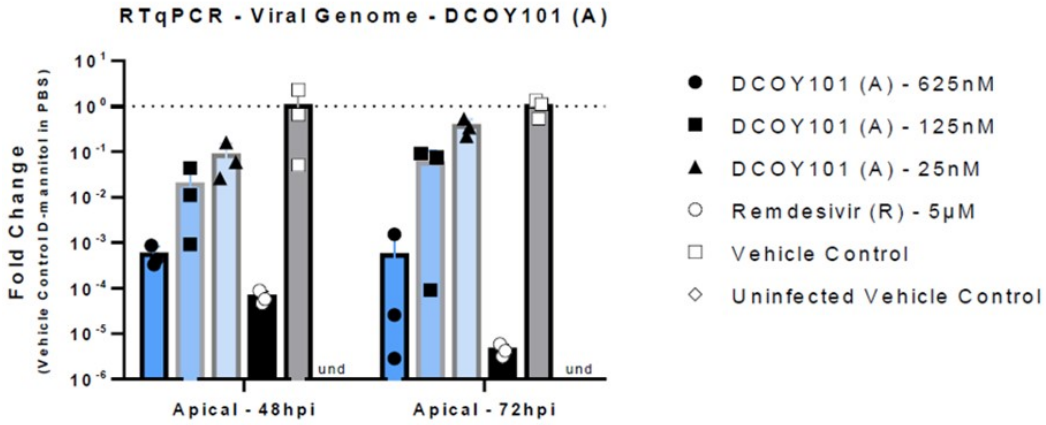


DCOY101 Inhibits Infection in a Human SARS-CoV-2 HAE-ALI Infection Model:

The pan-Coronavirus peptide conjugate DCOY101 prevented infection in the HAE model HAE from Epithelix with dose response from 25 nM, 125 nM to 625 nM. Compound was delivered apically (on the air side) at the same time as the viral challenge (prophylactic treatment). Doses selected covered previous *in vitro* efficacious

concentration range and hamster PK nasal levels. DCOY101 demonstrated a dose dependent decrease in viral load measured at 48- and 72-hours post-infection, as seen in figure 5 below. Viral load was reduced by ~4 logs compared to vehicle treatment. Remdesivir was used as a positive control for this experiment, as it is approved for use in hospitalized COVID-19 patients. Remdesivir gave significant viral inhibition as expected based on previous prophylactic HAE-ALI results.[16] Remdesivir works by a different mechanism of action, was delivered basolaterally (in the media to simulate IV injection) in this assay and is dosed 8x higher than DCOY101.

Figure 5: Activity of DCOY101 in the Human Airway Epithelial Model



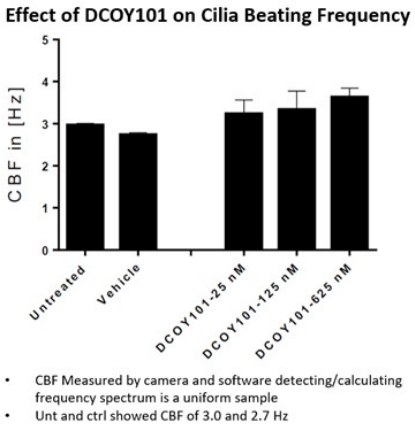
The dose responsive antiviral efficacy shown in the above graph is due to DCOY101's anti-fusion mechanism, rather than toxicity in the HAE system. Toxic effects on the cells were measured with five different endpoint assays. To summarize four of the toxicity assessments: there was no impact on the cellular junctions and integrity of the epithelial cell layer as measured by trans-epithelial electrical resistance , no increase of lactate dehydrogenase as a measure of ruptured plasma membranes, no induction of inflammatory response as measured by

IL-8 secretion, and no impact on the mucociliary clearance after treatment with DCOY101. In addition, Figure 6 shows that DCOY101 had no impact on the function and frequency of the cilia as measured by calculating the

[16] Antiviral Research (2021) 192:105122

frequency of cilia beating in untreated cells compared to cells treated with three dose levels of DCOY101. Ciliated cells in the nasopharynx are the primary targets for SARS-CoV-2 fusion and entry.

Figure 6: Maintenance of Cellular Function as a Toxicity Measure in HAE



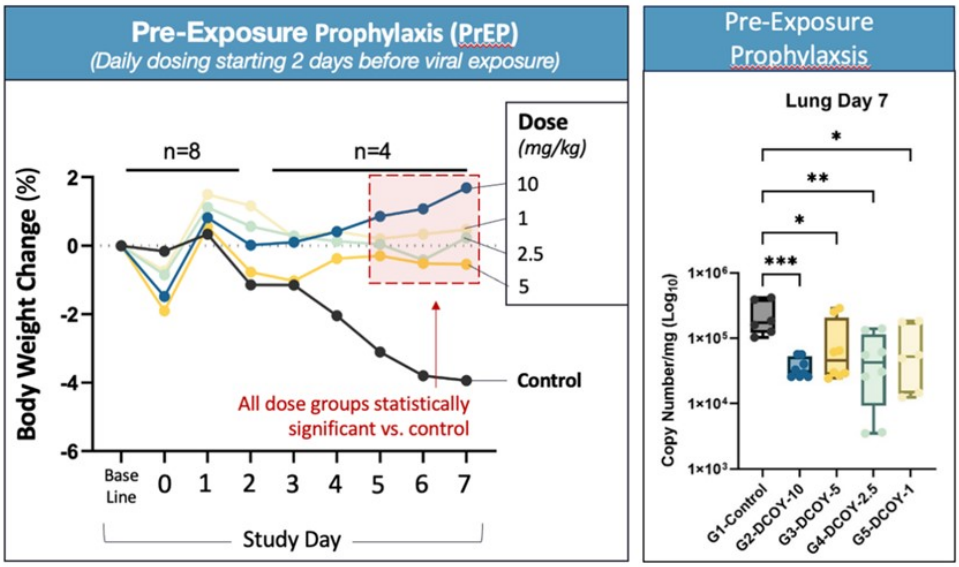
In vivo Efficacy Evaluations:

Administration of DCOY101+ demonstrated decreased pathological body weight loss and viral infectious genomes and live virus particles *in vivo* in an intranasal prophylactic (dosing begins before viral exposure) and post-exposure prophylactic (dosing begins after exposure but before symptoms) Syrian hamster model of SARS-CoV-2 delta variant infection.

Syrian Golden hamsters are susceptible to SARS-CoV-2 infection, and will become sick, although they typically clear the infection by 7 days and infection is not fatal. SARS-CoV-2 will infect the hamster nose, and cause lesions in the lungs by day 4. Hamsters will lose weight, which is thought to be equivalent to a human showing symptoms.

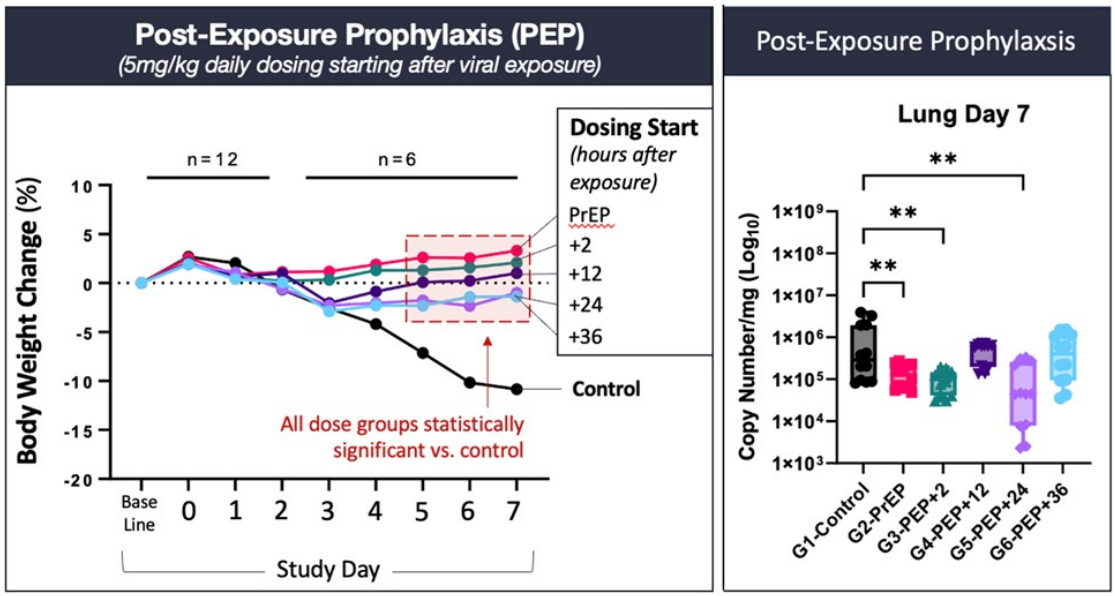
Two studies were conducted with DCOY101. In the first study (Pre-Exposure Prophylaxis or PrEP) hamsters were dosed intranasally with peptide conjugate at different dose levels in a liquid formulation once a day, starting two days before they were given a dose of the delta SARS-CoV-2 virus and continuing until day 7 (Fig. 7). The administered viral inoculum gives a high level of viral replication and pneumonia in hamsters, with body weight loss evident between 24 and 48 hours as a pathology symptom. By day 7 animals treated with vehicle alone had lost 5-10% of their body weight. Animals treated with DCOY101 were able to maintain body weight, or even gained weight at the highest dose level tested, indicating protection from viral effects. The experiment was terminated on day 7 for assessment of viral levels in nose and lungs. Measurements of viral genomes (which represents live and dead virus) and live virus particles were measured in both studies on days 2 and 7. Viral load showed significant reduction in all dose levels tested, measured by RT-qPCR on a log scale as noted in figure 7.

Figure 7: DCOY101 Prevents SARS-CoV-2 Infection in the PrEP Syrian Hamster Model



In the second study PEP hamsters were dosed intranasally with DCOY101 beginning at various timepoints after the virus was given to the animals intranasally (2, 12, 24 and 36 hours post challenge – Figure 8). As seen previously, control animals treated with vehicle alone began to lose weight between 24 and 48 hours after viral administration. Animals treated with DCOY101 maintained their weight throughout the study across all the timepoints tested, even when dosing did not start until 36 hours after the virus, which is within the timeframe when the hamsters are showing the body weight loss symptom. Based on this data, it is possible that Decoy's Pan-Coronavirus intranasal peptide conjugate could also have activity as a therapeutic in addition to a prophylactic treatment.

Figure 8: DCOY101 Prevents SARS-CoV-2 Infection up to 36 hours Post Exposure



Preclinical Research Plans

Decoy has demonstrated *in vitro* activity across all the human infecting coronaviruses it can test and has observed significant antiviral activity across this viral family. SARS-CoV-2 infection can be significantly inhibited with prophylactic treatment of DCOY101 in the human organoid HAE-ALI model, and *in vivo* in the pre-exposure and PEP hamster models.

Lead Optimization:

The IMP^{3}ACT Platform acts as an iterative feedback loop and incorporates data from in vitro experiments to improve the design parameters of the candidate peptides. Typical data that may be used to guide the AI and ML systems consists of SPR binding potency, cell-based activity via pseudotype or live virus assays, and assessment of molecular parameters of the peptide. By using the experimental data to train the ML engine, more potent and drug-like peptide binders can be designed over time, with multiple parameter optimization simultaneously. This ML/AI-enhanced approach not only reduces the costs associated with combinatorial research investigations but also allows for the manufacturing of the lead drug candidate at a lower cost due to the improvements in speed and scale for peptide synthesis. Moreover, the platform achieves peptide conjugate manufacturing readiness within significantly shorter timelines compared to traditional drug development processes, aiming to eventually meet or exceed a 100-day goal for vaccine manufacture.

Use of Physiologically Relevant Human Tissue Models:

The HAE model uses primary differentiated human biopsy tissue with appropriate architecture and cellular complexity, and allows infections from standard respiratory viruses including RSV, SARS-CoV-2 and influenza.[17] The kinetics of SARS-CoV-2 replication in these HAE-ALI cultures is very similar to that observed in humans, as the viral load peaks between days 4 and 8,[18] which is consistent with the viral peaks observed in the human challenge study. Decoy believes that this human-based model system will be useful to optimize the pharmacokinetic properties of its peptide conjugates, with the expectation that human nasal tissue will provide the most predictive tool versus rodent

[17] Antiviral Research (2018) 156:72-79.
[18] Antiviral Research (2021) 192:105122.

animal models. This medium-throughput system will allow careful evaluation of tissue residence time and the effect of formulation excipients.

CMC

Drug Substance: Continuous Manufacturing – IMP³ACT Platform:

Decoy utilizes a continuous manufacturing technology which, by thoughtful design and differentiation of chemically active sites on the target molecule, allows for complete manufacture of the full target compound from beginning to end without the need for any intermediate isolation or purification. This synthesis is a continuous flow chemical process in which both the peptide component and the final cholesterol linker/anchor are assembled in one continuous operation. The desired compound is isolated only after the target is fully assembled.

The advantages of the continuous manufacturing process are several:

1. A single continuous operation to produce a very complex molecule.
2. Overall improvement of speed of the synthesis
    - Continuous manufacturing process time to final product is approximately 5-6 days. This is in contrast with similar compounds requiring numerous isolations and purifications taking approximately 8 weeks to manufacture and isolate.
3. In-process analytical and quality checks can be performed to check on progress of the assembly of the target molecule.
    - High quality of the process output is assured by continuous monitoring of the outcome of combined unit operations.
4. Simplicity of overall process.
    - Instead of as many as roughly 70-unit operations and numerous purifications, this continuous process requires only material inputs and a single isolation and purification.

Drug Substance: Distributed Manufacturing - IMP³ACT platform

Decoy is aware of FDA's Framework for Regulatory Advanced Manufacturing Evaluation program to support ongoing initiatives for prioritized advanced manufacturing technologies. Specific steps include:

- Continuing to develop guidance, as appropriate, to clarify areas of regulatory uncertainty, including the following proposed draft guidance: Considerations for Complying with 21 CFR 211.110, Approaches to Meeting cGMP Requirements for Distributed Manufacturing, in early 2025; and
- Engage participants in the Center for Drug Evaluation and Research's Emerging Technology Program and the Center for Biologics Evaluation and Research's Advanced Technologies Team ,which are developing distributed manufacturing technologies and visit development sites.

Decoy projects that IMP³ACT, described above, can become a modular, distributed manufacturing platform if the following process development criteria are met:

1. Experience with multiple product manufactures enables continuous processing from start to finish to be optimized to maximize yield and purity of the final product.
2. This experience leads to an understanding of the critical process parameters, variables and attributes affecting product quality which can be applied to efficient continuous processing.
3. Robust and predictive in-process controls are developed.
4. Process concentrations are high.

5. Final purification and isolation of the agent produced can be made efficient and robust; and

6. The above criteria having been met, modular, portable standalone manufacturing skids with modest utility requirements are assembled and shown to be viable for the process.

It is Decoy's understanding that this type of modular, distributed manufacturing capability has been demonstrated previously for vaccine production "in-country" where the vaccines are urgently required. Decoy proposes developing a similar, modular, portable continuous manufacturing platform which can be used "in-country" where viral outbreaks occur, and patients are needing treatment. For the purposes of this modular, distributed system, it is Decoy's intent that the process can be made relatively straightforward so that deep knowledge of chemical processing is not required to successfully produce needed medicines.

Drug Product

With respect to drug product development activities, Decoy is developing and optimizing multiple nasal candidate formulations containing its peptide conjugates, including both liquid and dry powder-based formulations. Decoy has conducted multiple studies both internally and in collaboration with CMOs demonstrating the suitability for inclusion of its peptide conjugates in shelf-stable aqueous-based nasal formulations containing typical pharmaceutical excipients (osmotic agents, pH modifiers, preservatives, mucolytic agents, etc.) and has identified multiple lead formulation candidates. Decoy has also demonstrated the suitability for delivery of its nasal solution formulation candidates at therapeutic doses via conventional nasal spray devices, such as the VP7 Spray Pump and Unidose Liquid Nasal Spray devices available from Aptar Pharma Inc. ("Aptar"). Additionally, Decoy is developing dry powder-based formulations containing its peptide conjugates for nasal delivery via nasal dry powder devices such as the Unidose Powder Nasal Spray device available from Aptar.

Clinical Development Plan

Decoy expects to file an IND for its optimized pan-Coronavirus peptide conjugate within the first half of 2026 and subsequently, if approved, initiate a Phase 1 trial shortly thereafter. Decoy's planned Phase 1 trial is expected to be a randomized, placebo-controlled trial with a part A consisting of single ascending daily intranasal dose and multiple ascending daily dose in up to 40 healthy volunteers, followed by part B in which a 12- healthy volunteer cohort will be given an intranasal daily dose for 28 days.

The primary trial endpoints are expected to be able to determine the safety and local and generalized tolerability of the optimized clinical candidate administered daily as an intranasal spray. Secondary endpoints are expected to include evaluation of the pharmacokinetic profiles in the nose and oropharyngeal cavity over a 12-hour period. Decoy plans to also characterize the device delivery, mucociliary clearance and nasal residence time.

Decoy anticipates taking 2 dose levels into a Phase 2 proof of concept human challenge trial with up to 250 healthy volunteers. In this trial healthy volunteers are administered SARS-CoV-2 under carefully controlled and monitored conditions. Preventative and therapeutic compounds are tested to establish the relationship between pharmacokinetics and activity.

Other Indications for Decoy's Pan-Coronavirus Antiviral

Decoy believes there may be opportunities to develop DCOY101+ in additional indications, including:

- **Inhaled COVID-19 Therapeutic:** As shown in Figure 8, DCOY101 has demonstrated activity in hamsters against SARS-CoV-2 infection even when administered up to 36 hours after viral challenge, when significant symptoms have emerged (body weight loss). Decoy believes DCOY101+ may have utility as a COVID-19 treatment alternative to Paxlovid with a significantly superior drug-drug interaction profile. This could be of benefit to immunocompromised, high-risk, and elderly patients that are often already taking drugs that are contraindicated to Paxlovid.

- **Middle Eastern Respiratory Syndrome ("MERS") Therapeutic:** DCOY101+ has been shown to be active against the MERS-CoV coronavirus in live virus cell based assays, the virus that causes MERS. The symptoms of MERS range from mild respiratory illness to severe disease with shortness of breath and

pneumonia, and respiratory failure. Approximately 35% of reported cases have resulted in death, a rate much higher fatality rate than SARS-CoV-2.

- **Broad Respiratory Antiviral (Flu/COVID-19/RSV)**: Infectious respiratory diseases, particularly influenza, RSV, and SARS-CoV-2, continue to pose significant threats to global public health, leading to substantial morbidity and mortality worldwide. Despite advancements in antiviral therapies, the emergence of viral variants and the lack of broad-spectrum treatments remain major challenges in combating these respiratory pathogens effectively. Therefore, there is an urgent need for innovative strategies to develop potent and versatile antiviral agents capable of targeting multiple viral strains and providing broad protection against respiratory infections. A single peptide-conjugate therapeutic active against the major respiratory viruses from these 3 viral families with an excellent safety profile could fill a significant unmet medical need, particularly in immunocompromised patients and children.

Clinical Rationale and Disease Description

Globally, acute lower respiratory tract infections ("LRTI") have been among the top three causes of death and disability among both children and adults.[19] It is estimated that LRTIs cause nearly 4 million deaths annually and are a leading cause of death in children under 5 years old.[20] Viruses are estimated to be causative in up to 50% of these respiratory infections, with influenza A and B, RSV A and B, and coronaviruses being identified often. The syndromes of LRTI in children include bronchiolitis, exacerbations of asthma or wheezing, croup, and pneumonia, and viruses overlap in terms of which syndromes they cause, making it hard to identify a causative virus based on symptoms alone.

A recent study looked at the burden of community-onset LRTI in hospitalized adults over 18 in New York City prior to the COVID-19 pandemic. Out of a total of 4232 patients, 51% were > 65 years old. The virus percentage was as follows:

- Influenza (any) 20.2%
- RSV 9.8%
- RSV+ Human parainfluenza viruses + Human Metapneumovirus 26.5%
- Coronaviruses (all) 12.8% (not including SARS-CoV-2; study was Oct 2017-Sept 2019)

This dataset identifies that non-influenza viruses including the paramyxoviruses and non-SARS-CoV-2 coronaviruses are a significant cause of LRTI severe enough to lead to hospitalization, with a higher population-based incidence, significantly more ICU admissions, and higher in-house mortality.[21] Compared to the other viruses, the coronavirus 229E had the highest mortality rate at 12.3%. Among all the viruses studied, the combined coronaviruses had the highest rates of ICU admission and the highest mortality rates, including in the 18-49 and 50-64 age ranges.

A study from 2015-2018 in Canada on adult patients with ILI who were hospitalized the viral cause was determined to be:[22]

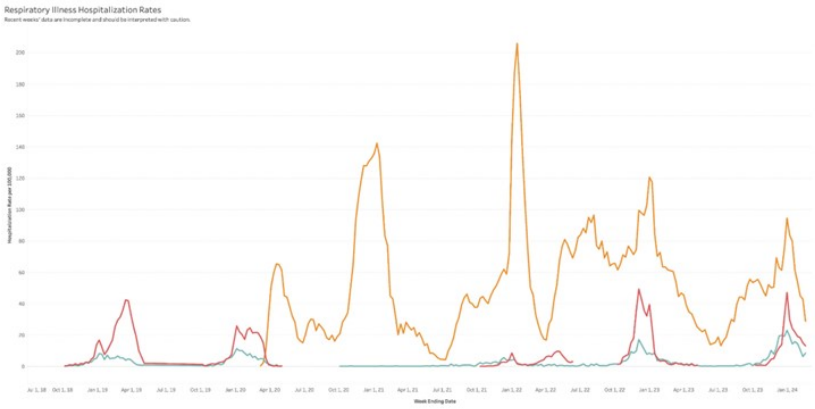
- Influenza 45.4%, 6.5% mortality by day 30
- RSV 12.9%, 9.5% mortality by day 30
- Coronavirus 8.2%, 9.2% mortality by day 30

[19] Forum of International Respiratory Societies. 3rd Edition. European Respiratory Society; 2021. The Global Impact of Respiratory Disease. Accessed February 27th, 2024.
[20] Lancet Infect Dis 2018; 18:1191-1210
[21] Influenza Other Respi Viruses. 2021;15:670-677.
[22] CMAJ. 2021; 193:E439-46. Doi: 10.1503/cmaj.201748.

Patients with non-influenza viruses were younger (mean 66.4 years old) and were more likely to be immunocompromised (30.3%). Additionally, 14.6% of non-influenza viruses were acquired in the hospital (nosocomial infections) rather than in the community. This was particularly true for coronaviruses, where 20% were hospital acquired, a higher rate than any other virus. Protection against institutional (hospital and long-term care facility) transmitted respiratory viruses is an unmet medical need.

Before the SARS-CoV-2 pandemic as shown by the two studies above, coronaviruses were a lower percentage of the overall total of LRTI hospitalizations compared to RSV and influenza. Now, with COVID-19, hospitalizations due to COVID-19 eclipse those from the other viruses as shown in Fig 9.

Figure 9: CDC hospitalization burden of Influenza, RSV and COVID-19



Weekly hospitalizations per 100,000 people in the United States. Covid-19 in yellow, influenza in red, RSV in blue. Data: *CDC*. Image: Benjy Renton for *Inside Medicine*.

It is evident that pneumonia prevention and treatment would have a significant impact on LRTI morbidity and mortality, in the United States and globally, in adults and children.

Current Treatment Landscape and Opportunity

Current medical approaches to alleviate disease burden from common viral LRIs include vaccination and antiviral treatment, where applicable. Vaccination, which can provide a cornerstone of antiviral protection, seems to be decreasing globally. Influenza vaccination among healthcare professionals increased during the COVID-19 pandemic up to ~90% coverage, but since then has decreased to 81% in the 2022-23 influenza season. Reports indicate that by late 2023, only 14% of American adults elected to get the latest SARS-CoV-2 vaccine, even though research indicated that vaccinated individuals were 54% less likely to get COVID-19. The recently approved RSV vaccine is only approved for certain populations, so widespread vaccine uptake is difficult to measure, but appears to be substantially less that the rate for flu.

Antiviral medications for influenza such as Tamiflu, Relenza, and Repivab can be used for treatment of influenza, and Paxlovid for the treatment of SARS-CoV-2. However, the influenza drugs are subject to drug resistance, and Paxlovid is underutilized because of the possibilities of drug-drug interactions. The reluctance of society to maintain up-to-date vaccinations can have significant repercussions on public health and the management of infectious diseases, among these increased disease burden, risks of outbreaks and epidemics, and increased transmission of resistant strains.

Decoy's peptide-conjugate therapeutic that treats LRIs from three major respiratory endemic and epidemic viruses would be unprecedented and could fill a significant medical need given the morbidity and mortality associated with LRIs globally.

Decoy's Solution

Decoy intends to explore the possibility of combining fusion inhibitory peptides for SARS-CoV-2 (*coronaviruses*), RSV (*paramyxoviruses*) and flu (*orthomyxoviruses*) in a single molecule. Decoy plans to investigate several approaches to optimize breadth of activity.

Mechanism of Action

Figure 10: Conservation of the 6-helix bundle across class I fusion proteins from 3 viral families

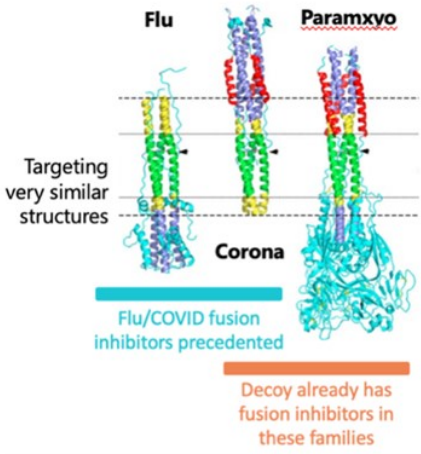


Figure 10 adapted from Igoneta, S. et. al., Proc Natl Acad Sci U S A. 2011 Dec 13;108(50):19967-72. doi: 10.1073/pnas.1108910108.

Decoy is targeting the conserved fusion machinery common to influenza A&B, paramyxoviruses (RSV A & B, hMPV, hPIV) and coronaviruses (SARS-CoV-2, OC43, NL63). Decoy believes a single molecule that targets all three major respiratory viral families is possible, given the highly conserved protein structure of the 6-helix post-fusion bundle common to these viruses as shown in Figure 10. Figure 10 illustrates the targeted viral fusion machinery across these viruses, emphasizing the conserved coiled-coil regions critical to Decoy's inhibitor design. By focusing on this shared mechanism, Decoy's project aims to pioneer a versatile antiviral agent, significantly impacting global health by mitigating the LRTI threat posed by these viruses.

Summary of Proof-of-Concept Preclinical Data

Significant progress has been made with Decoy's leading antiviral peptide conjugate series, DCOY101+, which has shown strong *in vitro* effectiveness against all tested SARS-CoV-2 variants and other human coronaviruses like MERS, SARS-CoV-1, OC43, and NL63 (see Fig. 3,5). *In vivo*, DCOY101+ has demonstrated antiviral effects and maintained therapeutic levels for over 8 hours when administered intranasally in Syrian golden hamsters- (Figures 7, 8).

Recently, Decoy's rapid discovery engine has produced broad-spectrum inhibitors against paramyxoviruses, with promising proof of concept *in vitro* results against RSV-A, RSV-B, and HPIV3 (Fig. 11). Synthesis of these novel peptide conjugates was completed in just four days with the "All-in-one" synthesis process.

Figure 11: Activity of Decoy's Peptide Conjugate Antivirals Against 3 viruses from the Paramyxovirus Family

A.

Compound	RSV_{A2}			$RSV_{B\ 18537}$		
	EC_{50} (μM)	TC_{50} (μM)	Therapeutic Index	EC_{50} (μM)	TC_{50} (μM)	Therapeutic Index
TCM353121 (nM)	0.005	>100	>20000	0.03	>100	>3333
DCOY3001	<0.04	5.7	>143	0.04	5.91	148
DCOY3002	0.17	>10	>58.8	0.87	>10	>11.5
DCOY3003	0.2	>10	>50	1.55	>10	>6.45
DCOY3004	0.05	8.46	169	<0.04	>10	>250

B.

Compound	$hPIV_{C243}$		
	EC_{50} (μM)	TC_{50} (μM)	Therapeutic Index
Ribivarin (ug/mL)	17.8	>100	>4.57
DCOY3001	6.5	>10	>1.53
DCOY3002	0.5	>10	>20
DCOY3003	0.05	1.89	37.8
DCOY3004	>5.29	5.29	---

DCOY3002: potent activity (< 1 uM) against all 3 viruses

Therefore, Decoy has demonstrated peptide conjugate molecules with broad-based antiviral POC against two of the three respiratory viral families Decoy is targeting in this program. Based on Decoy's in-silico tools, Decoy believes it will be possible to design a single molecule that also targets influenza in addition to coronaviruses and paramyxoviruses.

Clinical Development Plan

Decoy intends to follow a similar structure for this clinical program as for its *pan-Coronavirus* prophylactic peptide-conjugate. A Phase 1 trial would focus on the safety, local and general tolerability of an inhaled formulation of the multi-viral family peptide conjugate. Phase 2 would include a healthy volunteer human challenge trial using multiple arms to interrogate all three viral families, flu A, RSV and SARS-CoV-2 to determine the PK/efficacy relationship and establish proof of concept. Each of these viruses has been previously studied in human challenge trials.

Potential Future Indications

Upon establishing proof of concept as outlined above, Decoy believes there would be several attractive commercial indications for this candidate, including:

- Therapeutic treatment of early LRTIs in immunocompromised patients via inhaled administration. Mortality rates in some severely immunocompromised patient populations, such as patients undergoing cancer treatment or post-transplant patients, can be as high as 50%[23];
- Prophylactic use in highly immunocompromised patient populations, including immunocompromised pediatric populations;
- Therapeutic use in large populations that are susceptible to LRTIs, including people who are 65+ or who are suffering from high-risk conditions such as Type II diabetes, chronic kidney disease , congestive heart failure, and chronic obstructive pulmonary disease; and
- Broad use among otherwise healthy populations during seasonal surges in 'influenza-like illness.'

[23] Viral Infections of Humans DOI 10.1007/978-1-4899-7448-8_26.

GPCR-Targeted Peptide Conjugate for CRC and other GI Tumors

GPCRs are anchored in the cell membrane and are triggered by extracellular chemicals (ligands) that activate internal signal transduction to drive cellular responses through a set of 'G-proteins' and/or arrestins inside the cell. Their endogenous ligands include odors, hormones, neurotransmitters, and chemokines, with structures ranging from photons, amines, carbohydrates, lipids, proteins, and peptides. GPCRs have been implicated in many diseases, such as Type II diabetes mellitus, obesity, depression, cancer, Alzheimer's disease, and many others.[24]

While not classic driver mutations, several GPCRs with natural α-helical peptide ligands have been reported to be overexpressed in colon tumors compared to normal tissue[25]. Recent large-scale expression GPCR profiling has shown signatures of large numbers of GPCRs across different tumor types upregulated when compared to normal tissue. The findings suggest that GPCRs over expressed in cancer are often critical contributors to their malignancy and that this may be an underexplored area for targeting cancer.

The structure of GPCRs is well conserved, with a defined architecture, and the ligand binding sites are on the outer cell membrane. Over 100 GPCRs have endogenous peptide ligands, providing an excellent natural starting point for Decoy's innovative IMP^{3}ACT design platform.

While at the exploratory stage, Decoy has identified an initial GPCR target of interest that is reportedly expressed in intestinal polyps and in 100% of all stages of colon tumors, including metastases and 5-FU resistant tumors. This target has two identified naturally occurring α-helical peptide ligands, and treatment of colon tumor cell lines and xenografts with this peptide alone has demonstrated anti-cancer activity. Decoy believes that a peptide-conjugate based on this ligand, with improved pharmacokinetic and drug-like properties, may have potential as a candidate for conjugation to a cytotoxic payload or a radionucleotide for diagnostic imaging and therapeutics , like somatostatin.

Initial Indication

CRC therapies have changed little over the last decades, with mainstay therapies continuing to revolve around 5-FU, platinum, and irinotecan combinations, typically with the addition of an anti-VEGF treatment. Only a small fraction of patients benefits from 'precision medicine' approaches based on specific biomarkers (for example, only 3-5% of CRC patients have an amplified HER2 are therefore eligible for the ADC, trastuzumab deruxtecan).

There is an urgent need for the identification of new cell membrane targets to create multiple precision treatments options for many colon cancer patients, including late stage metastatic and drug resistant tumors.

Decoy's Solution

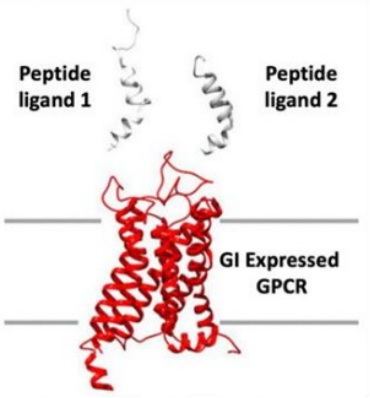
A peptide conjugate that targets a GPCR expressed universally in CRC tumors, including metastatic and SOC resistant tumors and delivers into the cell a radionuclide, a cytotoxic drug or a PROTAC payload would be a substantial addition to CRC precision medicines. The peptide conjugate may be administered through a SC injection with a depot formulation, as has been done for the somatostatin drugs, or may also be formulated as a pill for GI tract use. Oral bioavailability of peptide conjugates, while low, has been demonstrated with the GLP-1 inhibitors.

Biology and Mechanism of Action

This initial GPCR target has been reported to be expressed selectively in polyps and tumors of the colon, prostate, and pancreas. It has a typical structure with α-helical peptide ligands as shown in Figure 12.

[24] Sriram K. and P.A. Insel (2018) Mol Pharmacol 93:251-258.
[25] Insel PA, et. al., (2018) Front. Pharmacol. 9:431.doi: 10.3389/fphar.2018.00431.

Figure 12: Representative structure for GI targeting GPCR



The peptide ligands for this GPCR are reported to normally play a role in the central nervous system, with extremely low levels in systemic circulation. This may explain why colon tumors are not normally inhibited by these ligands. The natural half-life of these peptides is minutes, which may also explain the lack of activity. Therefore, these peptides are excellent candidates as starting points for Decoy's drug design engine.

Potential Future Indications

Decoy believes there are multiple potential additional indications for this type of therapeutic, including:

- **Treatment for familial adenomatous polyposis ("FAP").**
- **Diagnostic for FAP and colorectal cancer:** conjugated to an appropriate imaging radionucleotide in a manner like that done for somatostatin.
- **Additional therapeutic peptide-conjugate indications:** intestinal bowel disease and late stage/metastatic colon cancer.
- **Use in additional cancers:** depending on levels of GPCR expression, Androgen Insensitive Prostate Cancer and Glioblastoma multiforme.

Competitors and Competitive Advantage

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While Decoy believes that its technologies, knowledge, experience, and scientific resources provide it with competitive advantages, Decoy faces potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that Decoy successfully develops and commercializes will compete with existing therapies and new therapies that may become available in the future.

Decoy's potential competitors include large pharmaceutical and biotechnology companies, as well as specialty pharmaceutical and generic or biosimilar drug companies. Many of Decoy's competitors have significantly greater financial and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than Decoy does. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors compete with Decoy in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring products, product candidates or other technologies complementary to Decoy's programs.

Each of Decoy's pipeline candidates faces a unique but, in Decoy's view, favorable competitive landscape because of Decoy's emphasis on unique value propositions. Specifically:

- **COVID-19 Prevention & Treatment for Immune-Suppressed Patients:** Despite being four years from the beginning of the COVID-19 pandemic, there are still limited prophylactic options for people with highly suppressed immune function. The mRNA vaccines have been shown to be less effective for immune-suppressed patients[26], and Decoy believes this will also be true for the nasally delivered vaccines currently under development. Also, vaccine efficacy has been and will likely continue to be at risk from the evolution of the SARS-CoV-2 virus, and COVID-19 vaccine uptake has continued to decline significantly in the US[27]. Long-lasting antibody prophylactics such as Evusheld were initially effective but rapidly became obsolete due to viral evolution,[28] and this is likely for the new emergency use authorization approval, pemivibart. Decoy's therapeutic candidate is effective against all SARS-CoV-2 variants, and Decoy expects it to continue to be based on the limited evolution that has occurred to date in the portion of the SARS-CoV-2 genome Decoy is targeting. Given this, along with convenient administration and the fact that Decoy's strategy does not require a functional immune system, Decoy believes this therapeutic will deliver a unique solution for highly immune-suppressed patients in both the developed and developing worlds.

- **Broad Respiratory Antiviral (COVID-19/Flu/RSV):** There is significant competition in each of the areas of COVID-19, Flu, and RSV antiviral therapeutics, both from currently commercialized drugs and pipeline candidates. Also, while there are vaccines against these pathogens, their usage continues to be low. Decoy believes its strategy of being able to treat all three viruses, and potentially additional human *Coronaviruses* and *Paramyxoviruses* that cause influenza-like symptoms, with a single therapeutic will deliver a unique value proposition during seasonal surges of ILI. These illnesses can be personally disruptive to patients, and often lead to dangerous lower respiratory tract infections[29], especially in immune-compromised individuals. It is often challenging to identify respiratory viruses, so it is Decoy's belief that a therapeutic that can safely treat a large percentage of ILI-causing viruses would be a uniquely useful tool for healthcare providers.

- **GPCR-Targeted Conjugate for GI Tumors:** Several promising new treatments for metastatic colorectal cancer are emerging from recent clinical trials that may impact the competitive landscape. Immunotherapy combinations like botensilimab (anti-CTLA-4) and balstilimab (anti-PD1) have shown significant activity in microsatellite stable mCRC, a historically challenging "immunologically cold" subtype found in most patients. Newer anti-VEGFR treatments like fruquintinib have demonstrated modest improved overall and progression-free survival compared to placebo in refractory mCRC patients. Personalized medicine approaches, including biomarker-guided targeted therapies like ADCs are gaining traction. ADCs like trastuzumab deruxtecan is FDA approved for HER2-positive mCRC, while others such as telisotuzumab adizutecan (a c-MET targeting ADC) are showing promise in clinical trials. Recently two GPCR-targeting ADCs have shown activity in preclinical work: LGR5-MMAE and GPR56-duocarmycin. Decoy expects that there will be continued growth in this area due to the strong unmet medical need in this indication.

Intellectual Property

Decoy strives to protect its proprietary technology, inventions, improvements, platforms, program candidates, therapeutic candidates and components thereof, its methods of use and processes for their manufacture that Decoy believes are important to its business, including by obtaining, maintaining, defending and enforcing patent and other intellectual property rights for the foregoing in the United States and in foreign jurisdictions. Decoy also relies on trade secrets and confidentiality agreements to protect its confidential information and know-how and other aspects of its business that are not amenable to, or that Decoy does not consider appropriate for, patent protection.

[26] https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(23)00142-6/fulltext
[27] https://www.cdc.gov/respiratory-viruses/data-research/dashboard/vaccination-trends-adults.html
[28] https://www.cnbc.com/2023/01/27/covid-fda-pulls-evusheld-because-its-not-effective-against-subvariants.html
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3106235/

Decoy's future commercial success depends in part on its ability to:

- obtain, maintain, enforce and defend patent and other intellectual property rights for its important technology, inventions and know-how; preserve the confidentiality of its trade secrets and other confidential information;
- obtain and maintain licenses to use and exploit intellectual property owned or controlled by third parties
- operate without infringing, misappropriating or otherwise violating any valid and enforceable patents and other intellectual property rights of third parties; and defend against challenges and assertions by third parties challenging the validity or enforceability of Decoy's intellectual property rights, or Decoy's rights in Decoy's intellectual property, or asserting that the operation of Decoy's business infringes, misappropriates or otherwise violates their intellectual property rights.

Decoy's portfolio currently consists of solely owned patents and applications. As of December 31, 2024, there are 6 patent families covering compositions of matter, manufacturing and uses related to its business.

Patent Prosecution

A patent application filed under the Patent Cooperation Treaty ("PCT") is not eligible to become an issued patent until, among other things, Decoy files one or more national stage patent applications in the jurisdictions in which it seeks patent protection and do so within prescribed timelines of the PCT patent application's priority date. These prescribed timelines are generally 30 months, 31 months or 32 months, depending on the jurisdiction. To date, Decoy has filed national stage applications in Australia, Canada, Europe and New Zealand. If Decoy does not timely file any national stage patent applications, it may lose its priority date and any potential patent protection on the inventions disclosed in such PCT patent application.

Moreover, a provisional patent application is not eligible to become an issued patent. A provisional patent application may serve as a priority filing for a non-provisional and/or PCT patent application Decoy files within 12 months of such provisional patent application. If Decoy does not timely file non-provisional or PCT patent applications, it may lose its priority date with respect to its existing provisional patent applications and any potential patent protection on the inventions disclosed in its provisional patent applications.

While Decoy intends to timely file additional provisional patent applications and PCT applications, as well as national stage and non-provisional patent applications relating to its provisional applications or PCT patent applications, Decoy cannot predict whether any of its patent applications will result in the issuance of patents. If Decoy does not successfully obtain patent protection, or if the scope of the patent protection Decoy or its licensors obtain with respect to Decoy's therapeutic candidates or technology is insufficient, Decoy will be unable to use patent protection to prevent others from using Decoy's technology or from developing or commercializing technology and products similar or identical to Decoy or other similar competing products and technologies. Decoy's ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of its technology, inventions and improvements, either directly or indirectly, will depend in part on Decoy's success in obtaining, maintaining, defending and enforcing patent claims that cover its technology, inventions and improvements.

The patent positions of companies like Decoy are generally uncertain and involve complex legal and factual questions. The protection afforded by a patent varies on a product-by-product basis, from jurisdiction-to-jurisdiction, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of patent term adjustments and regulatory-related patent term extensions, the availability of legal remedies in a particular jurisdiction, and the validity and enforceability of the patent. Patent laws and related enforcement in various jurisdictions outside of the United States are uncertain and may not protect Decoy's rights to the same extent as the laws of the United States. Changes in the patent laws and rules, whether by legislation, judicial decisions or regulatory interpretation, in the United States and other jurisdictions may have uncertain affects that could improve or diminish its ability to protect its inventions and obtain, maintain, defend and enforce its patent rights, and could therefore affect the value of its business in uncertain ways.

The area of patent and other intellectual property rights in biotechnology is evolving and has many risks and uncertainties, and third parties may have blocking patents and other intellectual property that could be used to prevent Decoy from commercializing its platform and therapeutic candidates and practicing its proprietary technology. Decoy's patent rights may be challenged, narrowed, circumvented, invalidated or ruled unenforceable, which could limit its ability to stop third parties from marketing and commercializing related platforms or therapeutic candidates or limit the term of patents that cover its platform and any therapeutic candidates. In addition, the rights granted under any issued patents may not provide Decoy with protection or competitive advantages against third parties with similar technology, and third parties may independently develop similar technologies.

Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any of Decoy's therapeutic candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any competitive advantage provided by the patent. For this and other risks related to Decoy's proprietary technology, inventions, improvements, platforms and therapeutic candidates and intellectual property rights related to the foregoing, please see the section entitled "*Risk Factors— Risks Related to the Discovery, Development and Commercialization of Product Candidates by Decoy*."

Patent Term

The term of individual patents depends upon the laws of the jurisdictions in which they are obtained. In most jurisdictions in which Decoy files, the patent term is 20 years from the filing date of a PCT patent application or, if a PCT application is not filed, the earliest date of filing of the first non-provisional patent application to which the patent claims priority. However, the term of U.S. patents may be extended or adjusted for delays incurred due to compliance with FDA requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office ("USPTO"). For example, in the United States, a patent claiming a new chemical entity ("NCE") or biologic product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") for up to five years beyond the normal expiration date of the patent. Patent term extension cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval of the product. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. For more information on patent term extensions, see "*Business—Government Regulation— Patent Term Restoration and Extension and Marketing Exclusivity*." In the future, if and when any therapeutic candidates Decoy may develop receive FDA approval, Decoy expects to apply for patent term extensions on issued patents covering those therapeutic candidates. Moreover, Decoy intends to seek patent term adjustments and extensions for any of its issued patents in any jurisdiction where such adjustments and extensions are available. However, there is no guarantee that the applicable authorities, including the USPTO and the FDA, will agree with Decoy's assessment of whether such adjustments and extensions should be granted, and even if granted, the length of such adjustments and extensions.

Trade Secrets

In addition to patent protection, Decoy also relies on trade secrets, know-how, unpatented technology and other proprietary information to strengthen its competitive position. Decoy currently, and may continue in the future continue to, rely on third parties for assistance in developing and manufacturing its products. Accordingly, Decoy must, at times, share trade secrets, know-how, unpatented technology and other proprietary information, including those related to its platform, with them. Decoy may in the future also enter into research and development collaborations with third parties that may require Decoy to share trade secrets, know-how, unpatented technology and other proprietary information under the terms of research and development partnerships or similar agreements. Nonetheless, Decoy takes steps to protect and preserve Decoy's trade secrets and other confidential and proprietary information and prevent the unauthorized disclosure of the foregoing, including by entering into non-disclosure and

invention assignment agreements with parties who have access to Decoy's trade secrets or other confidential and proprietary information, such as employees, consultants, outside scientific collaborators, contract research and manufacturing organizations, sponsored researchers and other advisors, at the commencement of their employment, consulting or other relationships with Decoy. In addition, Decoy takes other appropriate precautions, such as maintaining physical security of its premises and physical and electronic security of its information technology systems, to guard against any misappropriation or unauthorized disclosure of its trade secrets and other confidential and proprietary information by third parties.

Despite these efforts, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to Decoy's trade secrets or other confidential or proprietary information. In addition, Decoy cannot provide any assurances that all of the foregoing non-disclosure and invention assignment agreements have been duly executed, and any of the counterparties to such agreements may breach them and disclose Decoy's trade secrets and other confidential and proprietary information. Although Decoy has confidence in the measures it takes to protect and preserve its trade secrets and other confidential and proprietary information, they may be inadequate, Decoy's agreements or security measures may be breached, and Decoy may not have adequate remedies for such breaches. Moreover, to the extent that Decoy's employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for Decoy, disputes may arise as to Decoy's rights in any know-how or inventions arising out of such work. For more information, please see the section entitled "*Risk Factors— Risks Related to the Discovery, Development and Commercialization of Product Candidates by Decoy*."

U.S. Patent Term Restoration and Extension and Marketing Exclusivity

In the United States, a patent claiming a new biologic or pharmaceutical product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND and the submission date of the New Drug Application ("NDA") or Biologics License Application ("BLA"), plus the time between the submission date of the NDA or BLA and the ultimate approval date, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Marketing exclusivity provisions under the Federal Food, Drug, and Cosmetic Act (the "FDCA") also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a New Chemical Entity ("NCE"). A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA"), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extensions in the European Union and Other Jurisdictions

The European Union also provides for patent term extension through Supplementary Protection Certificates ("SPCs"). The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a drug. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained; and in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Key Relationships & Licenses

In June of 2020 Decoy entered a broad one-year, non-exclusive licensing agreement with the Massachusetts Institute of Technology related to developing potential treatments for COVID-19, using a variety available resources, services and technologies from the Institute. Additionally, in July of 2020, Decoy entered into a Sponsored Research Agreement and option agreement with Columbia University to evaluate a molecule to block the transmission of COVID-19, neither collaboration resulted in a licensing agreement for Decoy.

Decoy has attracted non-dilutive investments from the Bill & Melinda Gates Foundation, the Center for the Biologic Advanced Research and Development Authority and Johnson & Johnson through the U.S. Government's Blue Knight Program, with some additional support from the European Union's IMI-CARE Consortium and the Massachusetts Life Sciences Seed Fund.

Machine Learning and Artificial Intelligence computing support: Google AI Startup Program and the NVIDIA Inception Program including computing credits as well as hardware and software discounts.

Sales and Marketing

While Decoy is not a commercial-stage biotechnology company at this time, Decoy believes that the structure of its drug development pipeline and emerging trends in pharmaceutical marketing could allow Decoy to efficiently implement a commercial model capable of addressing high-revenue markets without building a traditional 'big pharma' sales organization.

Small, Specialized Sales Force

Many of the immune-suppressed, high-risk, or orphan cancer patient groups that would be key early commercial targets for Decoy's drug development candidates are typically served by specialist HCPs working in easy to identify and access medical settings. For example, in the United States:

- The great majority of solid organ transplants are performed at one of approximately 250 transplant centers[30]
- Leukemia/Lymphoma patients are typically associated with one of approximately 70 NCI-designated cancer centers[31]

Should one or more of Decoy's pipeline candidates reach commercialization, Decoy believes it will be feasible to build a small and specialized sales force that can work across its sales portfolio to target and access these patient settings in a financially efficient manner. This would enable Decoy to drive revenue growth while maintaining a cost-effective commercial and medical affairs footprint to effectively engage with key opinion leaders and specialists, particularly at cancer and transplant centers.

Emerging "Telehealth" Commercial Model

In addition, Decoy believes it will be well-positioned to implement an innovative commercialization strategy which leverages various emerging technological elements aimed at efficiently optimizing patient engagement,

[30] https://optn.transplant.hrsa.gov/about/search-membership/
[31] https://www.cancer.gov/research/infrastructure/cancer-centers

facilitating access to HCPs, and streamlining product delivery. Key components of such a commercial model could include:

- **Digital Patient Engagement:** Leveraging digital channels such as social media and paid search to efficiently educate patients about Decoy's products, ensuring broad reach and accessibility.
- **Telehealth Partnerships:** Collaborating with telehealth providers to enable convenient and immediate access to HCPs, complementing direct-to-consumer campaigns and facilitating seamless patient engagement.
- **At-Home Delivery:** Implementing a streamlined process for at-home delivery of Decoy's products following prescription, potentially facilitated through telehealth visits, enhancing patient convenience and adherence.
- **Streamlined Distribution:** Aligning with industry trends to establish a streamlined distribution strategy aimed at enhancing efficiency and optimizing gross to net.

Such an innovative commercial model would not only align with Decoy's status as an emerging biotechnology organization but also reflect broader industry trends. By integrating these various channels, Decoy would aim to orchestrate a streamlined patient journey, reducing the time and in-person contact requires for patients to access its therapies. This approach would not only mitigate the risks associated with transmission of infectious diseases for patients, but also enhance operational efficiency, resource utilization, and return on investment from cost of sales.

Manufacturing

Decoy does not currently own or operate manufacturing facilities to produce clinical or commercial quantities of its product candidates. Decoy relies, and expect to continue to rely, on third parties to conduct some or all aspects of its product manufacturing, research, preclinical and clinical testing, and these third parties may not perform satisfactorily or dedicate adequate resources to meet Decoy's needs.

Government Regulation and Product Approvals

Government authorities in the United States, at the federal, state, and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates, among other things, the research, development, testing, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of drugs in the U.S. to assure the safety and effectiveness of medical products for their intended use under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, denial of the ability to import and export certain products, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCP") to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current good manufacturing practices(" cGMP"), requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies and post-approval studies required by the FDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of the purity and stability of the API and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, may continue after the IND is submitted.

Companies usually must complete some long-term preclinical testing, such as animal tests of reproductive AEs and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the investigational product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition,

the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold.

Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA requirements in order to use the study as support for an IND or application for marketing approval.

In addition to the IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by Decoy based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, for public dissemination on its *ClinicalTrials.gov* website.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.
- Phase 4: Post-approval studies, which are conducted following initial approval, are typically conducted to gain additional experience and data from treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee and the sponsor of an approved NDA is also subject to annual product and establishment user fees. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses, an exception from the establishment fee when the establishment does not engage in manufacturing the product during a particular fiscal year, and an exception from the product fee for a product that is the same as another product approved under an abbreviated pathway.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is

sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as APIs), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Under the FDA Reauthorization Act of 2017 ("FDARA"), the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain drug applications, including applications for drugs in a shortage or drugs for which approval is dependent on remediation of conditions identified in the inspection report.

In addition, as a condition of approval, the FDA may require an applicant to develop a Risk Evaluation and Mitigation Assessment ("REMS"). REMS use risk minimization strategies beyond professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU may include, but is not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast-Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast-track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast-track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast-track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast-track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast-track application does not begin until the last section of the application is submitted. In addition, the fast track

designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. There is limited experience with accelerated approvals by the FDA based on intermediate clinical endpoints. However, the FDA has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the

FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, the FDA's regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), and its implementation regulations, as well as the Drug Supply Chain Security Act ("DSCSA"), which regulates the distribution of and tracing of prescription drugs and prescription drug samples at the federal level, and sets minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an ANDA to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug..."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing an NCE. For the purposes of this provision, an NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Under FDARA, a priority review track will be established for certain generic drugs, requiring the FDA to review a drug application within eight months for a drug that has three or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes the FDA to expedite review of "competitor generic therapies" or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing

by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Safety and Innovation Act ("FDASIA"), in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time. For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments.

In addition, FDARA requires the FDA to meet early in the development process to discuss pediatric study plans with drug sponsors. The legislation requires the FDA to meet with drug sponsors no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly responds to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which a generic (ANDA or 505(b)(2) NDA) applicant submitted a paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by a proposed generic product.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Those circumstances include instances in which another sponsor's application for the same drug product and indication is shown to be "clinically superior" to the previously approved drug. In this context, clinically superior means that the drug provides a significant therapeutic advantage over and above the already approved drug in terms of greater efficacy, greater safety or by providing a major contribution to patient care. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Under FDARA, orphan exclusivity will not bar approval of another orphan drug under certain circumstances, including if a subsequent product with the same drug for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FDCA, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. If not, it is generally a medical device.

Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices have the lowest level or risk associated with them, and are subject to general controls, including labeling, premarket notification and adherence to the Quality System Regulation ("QSR"). Class II devices are subject to general controls and special controls, including performance standards. Class III devices, which have the highest level of risk associated with them, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are subject to most of the aforementioned requirements as well as to premarket approval.

A 510(k) must demonstrate that the proposed device is substantially equivalent to another legally marketed device, or predicate device, which did not require premarket approval. In evaluating a 510(k), the FDA will determine whether the device has the same intended use as the predicate device, and (a) has the same technological characteristics as the predicate device, or (b) has different technological characteristics, and (i) the data supporting substantial equivalence contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and as effective as a legally marketed device, and (ii) does not raise different questions of safety and effectiveness than the predicate device. Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA concludes that a new device is not substantially equivalent to a predicate device, the new device will be classified in Class III and the manufacturer will be most likely required to submit a premarket approval ("PMA") to market the product.

Under the PMA application process, the applicant must demonstrate that the device is safe and effective for its intended use. This PMA approval process applies to most Class III devices, and generally requires clinical data to support the safety and effectiveness of the device, obtained in conformance with investigational device exemption regulations. The FDA will approve a PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose, and that the proposed manufacturing is in compliance with the QSRs. For novel technologies, the FDA will seek input from an advisory panel of medical experts regarding the safety and effectiveness of, and their benefit-risk analysis for the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process, though both processes can be expensive and lengthy, and require payment of significant user fees, unless an exemption is available.

Modifications to a 510(k)-cleared medical device may require the submission of another 510(k) or a PMA if the changes could significantly affect safety or effectiveness or constitute a major change in the intended use of the device. Modifications to a 510(k)-cleared device frequently require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a Special 510(k). If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, Decoy would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Procedures Governing Approval of Drug Products in the European Union

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an E.U. member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent Ethics Committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier

with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a product under European Union regulatory systems, an applicant must submit a marketing authorization application ("MAA"), either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all E.U. member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP"), established at the European Medicines Agency ("EMA"), is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various E.U. member states where such a product has not previously received marketing approval in any E.U. member states. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including Good Clinical Practice, are set forth in the Clinical Trials Directive 2001/20/EC and the Good Clinical Practice Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the E.U. member states. Under this system, approval must be obtained from the competent national authority of each E.U. member state in which a study is planned to be conducted. To this end, a clinical trial application is submitted, which must be supported by an investigational medicinal product dossier, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent Ethics Committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the European Union passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new E.U. clinical trials legislation was passed as a regulation that is directly applicable in all E.U. member states. All clinical trials performed in the European Union are required to be

conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of EMA, the new Clinical Trials Regulation will become applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the E.U. portal; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states; a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts—Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned; strictly defined deadlines for the assessment of clinical trial applications; and the involvement of the Ethics Committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Clinical Trials Regulation.

Data and Market Exclusivity in the European Union

In the European Union, NCEs qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be an NCE and the sponsor is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company can complete a full MAA with a complete database of pharmaceutical tests, preclinical tests and clinical trials and obtain marketing approval of its product.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Periods of Authorization and Renewals

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the

drug on the European Union market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the European Union. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinically relevant superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom (U.K.) voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the U.K. from the European Union will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the U.K. provides a notice of withdrawal pursuant to the E.U. Treaty. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. Additionally, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit Decoy's net revenue and results. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, ensuring adequate coverage and payment for Decoy's product candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require Decoy to conduct a clinical trial that compares the cost effectiveness of its product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in Decoy's commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain Decoy's business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA"), which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates that associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act (collectively the "ACA"), which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services , within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to physicians and teaching hospitals and information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Affordable Care Act(the "ACA"), which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to Decoy's potential product candidates are:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of average manufacturer price , for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the ACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the ACA without companion legislation to replace it, and a "skinny" version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures were passed by the U.S. Senate.

In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the ACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction ("CSR"), payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA.

A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain. Further, each chamber of Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures have been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. Congress will likely consider other legislation to replace elements of the ACA, during the next Congressional session. Decoy will continue to evaluate the effect that the ACA and its possible repeal and replacement could have on its business.

In August 2022, the Inflation Reduction Act of 2022 was signed into law and requires the federal government to negotiate prices for some high-cost drugs covered under Medicare, requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries, and caps Medicare

beneficiaries' out-of-pocket spending under the Medicare Part D benefit. Decoy will monitor this issue to determine the effects of this legislation on its business.

Human Capital Resources

As of December 31, 2024, Decoy had a total of eight full time employees. Decoy also utilizes the services of similarly sized team of contractors with whom it has on-going multi-year relationships, and a three-person scientific advisory board consisting of academic clinicians that can be considered key opinion leaders in the therapeutic areas in which Decoy plans to operate.

Decoy's human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating its existing and new employees, advisors and consultants. The principal purposes of Decoy's equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, to increase stockholder value and the success of Decoy by motivating such individuals to perform to the best of their abilities and achieve Decoy's objectives.

Properties

Decoy's corporate headquarters are located at One Broadway, 14th Floor, Cambridge MA 02142. Decoy leases laboratory space at the JLABs NYC, 101 6th Ave 3rd floor, New York, NY 10013. Decoy does not own any physical property, plant or labs. The combined company intends to maintain Salarius' headquarters in Houston, Texas.

Legal Proceedings

Decoy is not currently a party to any legal proceedings that, in the opinion of its management, are likely to have a material adverse effect on its business. Regardless of the outcome, litigation can have an adverse impact on Decoy because of defense and settlement costs, diversion of management resources and other factors.

History

Decoy was incorporated in the State of Delaware on April 17, 2020. Decoy is also registered to conduct business in Massachusetts and New York.

In addition, Decoy has a wholly-owned Canadian subsidiary, Decoy Drug Discovery Canada, Inc. which was incorporated on July 8, 2021. Decoy Drug Discovery Canada's primary activities have been related to sponsored research activities at the University of Toronto and The University of Waterloo. Decoy may conduct additional Canadian sponsored research and business activities in the future.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OF SALARIUS

The following discussion and analysis should be read in conjunction with Salarius' financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Salarius' actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set out under "Risk Factors" and elsewhere in this prospectus See "Special Note Regarding Forward-Looking Statements" elsewhere in this prospectus.

Overview

Salarius is a clinical-stage biopharmaceutical company that has been focused on developing effective treatments for patients with cancer with high, unmet medical need. Specifically, Salarius has been concentrated on developing treatments for cancers caused by dysregulated gene expression (i.e., genes which are incorrectly turned on or off). Salarius has two classes of drugs that address gene dysregulation: targeted protein inhibitors and targeted protein degraders. Salarius' technologies have the potential to work in both liquid and solid tumors. Salarius' current pipeline consists of two small molecule drugs: (1) SP-3164, a targeted protein degrader, and (2) seclidemstat ("SP-2577"), a targeted protein inhibitor.

Salarius has no products approved for commercial sale and has not generated any revenue from product sales. Salarius has never been profitable and has incurred operating losses in each year since inception. Salarius had an accumulated deficit of $80.5 million as of September 30, 2024. Substantially all of Salarius' operating losses resulted from expenses incurred in connection with Salarius' research and development programs and from general and administrative costs associated with Salarius' operations. As of September 30, 2024, Salarius had cash and cash equivalents of $3.3 million. During the three month ended September 30, 2024, Salarius sold 564,730 shares of its common stock in an at-the-market offering with gross proceeds of $1.5 million.

Salarius' financial statements are prepared using Generally Accepted Accounting Principles in the United States of America ("GAAP") applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Salarius' financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should Salarius be unable to continue as a going concern.

Salarius believes that there is presently insufficient funding available to allow Salarius to continue its current and planned clinical programs for a period exceeding 12 months from the date of this filing with the SEC.

The lack of revenue from product sales to date and recurring losses from operations since Salarius' inception raises substantial doubt as to Salarius' ability to continue as a going concern. Salarius will continue to require substantial additional capital to continue its operations and any clinical development activities that Salarius determines to advance and will need such additional capital within the next several months to continue to fund its operations beyond the first half of 2025. The amount and timing of Salarius future funding requirements will depend on many factors, including the results of our evaluation of strategic alternatives, and the Salarius board of directors' consideration of potential options to continue the clinical development for Ewing sarcoma in the future. Failure to raise capital as and when needed, on favorable terms or at all, would have a material negative impact on our financial condition and our ability to continues Salarius' operations.

Salarius may attempt obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, which will likely cause significant dilution to Salarius' existing shareholders. Salarius may also consider new collaborations or selectively partnering our technology. However, Salarius cannot provide any assurance that it will be successful in accomplishing any of our plans to obtain additional capital or be able to do so on terms acceptable to Salarius.

Program Development

SP-3164 – Targeted Protein Degradation

Salarius' plan has been to develop SP-3164 in high unmet need hematological indications and solid tumors. Salarius' goal was to file an investigational new drug ("IND") application with the U.S. Food and Drug Administration ("FDA") for SP-3164 in the first half of 2023, and begin a Phase 1/2 clinical trial in the second half of 2023, however the lack of funding required Salarius to curtail spending necessary to begin the clinical trial program.

SP-2577 Ewing Sarcoma

Ewing sarcoma is a devastating pediatric and young adult cancer for which there are no approved targeted therapies. The cause of Ewing sarcoma is a chromosomal translocation involving the Ewing sarcoma breakpoint region 1 gene and erythroblast transformation specific family genes, resulting in expression of a fusion oncoprotein. The resulting oncoprotein has been found to co-localize with LSD1 throughout the genome, making LSD1 an attractive therapeutic target for Ewing sarcoma.

On July 19, 2024, Salarius announced that it determined to close its ongoing Phase 1/2 clinical trial evaluating SP-2577 for Ewing sarcoma, including closing the remaining clinical trial sites. Salarius terminated the ongoing clinical trial in an effort to conserve cash while Salarius' board of directors continued its exploration of potential strategic alternatives. Salarius continues supporting The University of Texas MD Anderson Cancer Center ("MDACC") in MDACC's sponsored clinical trial evaluating SP-2577 in combination with azacytidine in adult patients with myelodysplastic syndromes and chronic myelomonocytic leukemia, which remains on partial clinical hold following a serious and unexpected grade 4 adverse event.

Evaluation of Strategic Alternatives

On August 8, 2023, Salarius announced that it retained Canaccord Genuity, LLC to lead a comprehensive review of strategic alternatives focusing on maximizing stockholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing, or other strategic transactions involving the company. In connection with the evaluation of strategic alternatives and in order to extend Salarius' resources, Salarius implemented multiple cost-savings plans to extend its expected cash runway in the first half of 2025.

Recent Developments

Entry into Merger Agreement with Decoy Therapeutics, Inc. ("Decoy")

On January 10, 2025, Salarius entered into an Agreement and Plan of Merger (the "Merger Agreement") with Decoy Therapeutics MergerSub I, Inc., a Delaware corporation and a wholly owned subsidiary of Salarius ("First Merger Sub"), Decoy Therapeutics MergerSub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Salarius ("Second Merger Sub"), and Decoy. Pursuant to the Merger Agreement, Salarius will combine with Decoy (the "Merger") by causing First Merger Sub to be merged with and into Decoy, with Decoy surviving the merger as a wholly owned subsidiary of Salarius (the "First Merger"). Immediately following the First Merger, Decoy will merge with and into Second Merger Sub, with Second Merger Sub being the surviving entity and continuing under the name "Decoy Therapeutics, LLC" as a wholly owned subsidiary of Salarius.

Results of Operations

Three months ended September 30, 2024 Compared to the Three months ended September 30, 2023

The following table sets forth the condensed consolidated results of Salarius' operations for the three months ended September 30, 2024 compared to September 30, 2023.

	Three months ended September 30,		
	2024	2023	$ Change
Research and development expenses	$ 137,234	$ 1,036,354	$ (899,120)
General and administrative expenses	869,237	1,495,831	(626,594)
Interest income, net and other	34,350	89,369	(55,019)
Net loss	**$ 972,121**	**$ 2,442,816**	**$ (1,470,695)**

Research and Development Expenses

Research and development expenses decreased during the three months ended September 30, 2024 compared to the same period in 2023 primarily related to the cost-savings plan implemented in the third quarter of 2023 which included a significant reduction in operating personnel.

	SP-2577		SP-3164	
	Three months ended September 30,			
Research and development costs by candidates and by categories:	2024	2023	2024	2023
Outsourced research and development costs	$ 87,044	$ 174,886	$ 2,281	$ 103,541
Employee-related costs	—	484,247	—	104,503
Manufacturing and laboratory costs	1,989	12,575	45,920	156,602
Total research and development costs	**$ 89,033**	**$ 671,708**	**$ 48,201**	**$ 364,646**

General and Administrative Expenses

General and administrative expenses were $0.9 million during the three months ended September 30, 2024, compared to $1.5 million for the three months ended September 30, 2023. The decrease is related to cost savings plan activities put in place in the third quarter of 2023 including lower personnel cost, insurance expense, and facility costs that were offset by higher legal expenses.

Nine months ended September 30, 2024 Compared to Nine months ended September 30, 2023

The following table sets forth the condensed consolidated results of Salarius' operations for the nine months ended September 30, 2024 compared to September 30, 2023.

	Nine months ended September 30,		
	2024	2023	$ Change
Research and development expenses	$ 594,683	$ 7,113,794	$ (6,519,111)
General and administrative expenses	3,650,920	4,810,449	(1,159,529)
Interest income, net and other	133,759	263,346	(129,587)
Net loss	**$ 4,111,844**	**$ 11,660,897**	**$ (7,549,053)**

Research and Development Expenses

Research and development expenses decreased during the nine months ended September 30, 2024 compared to the same period in 2023 primarily related to the cost-savings plan implemented in the third quarter of 2023 which included a significant reduction in operating personnel.

	SP-2577		SP-3164	
	Nine months ended September 30,			
Research and development costs by candidates and by categories:	**2024**	**2023**	**2024**	**2023**
Outsourced research and development costs	$ 258,417	$ 1,432,648	$ 56,609	$ 2,647,128
Employee-related costs	—	1,539,865	—	207,569
Manufacturing and laboratory costs	75,205	118,150	204,452	1,168,434
Total research and development costs	**$ 333,622**	**$ 3,090,663**	**$ 261,061**	**$ 4,023,131**

General and Administrative Expenses

General and administrative expenses were $3.7 million during the nine months ended September 30, 2024, compared to $4.8 million for the nine months ended September 30, 2023. The decrease is related to cost savings plan activities put in place in the third quarter of 2023 including lower personnel cost, a one-time reduction of bad debt expense, lower insurance and facility expenses, which were partially offset by contractual separation costs of $0.5 million incurred and paid during the nine month period ended September 30, 2024 in connection with our President and Chief Executive Officer ending his full-time employment and transitioning to a part-time consultant role, effective February 20, 2024 and slightly higher legal costs compared to the same period in the prior year.

Twelve months ended December 31, 2023 Compared to Twelve months ended December 31, 2022

The following table sets forth the consolidated results of our operations for the year ended December 31, 2023 compared to the year ended December 31, 2022.

	Year ended December 31		
	2023	**2022**	**Change**
Research and development expenses	**7,173,747**	**15,836,828**	**(8,663,081)**
General and administrative expenses	**5,721,197**	**7,138,403**	**(1,417,206)**
Change in fair value of warrant liability	**0**	**14,454**	**(14,454)**
Interest income (expense), net	**352,251**	**218,730**	**133,521**
Loss on impairment of goodwill	**—**	**8,865,909**	**(8,865,909)**
Net loss	**$ (12,542,693)**	**$ (31,607,956)**	**$ 19,065,263**

Research and Development Expenses

Research and development expenses were $7.2 million during the year ended December 31, 2023 compared to $15.8 million during the year ended December 31, 2022. This decrease of $8.7 million principally resulted from the

cost savings plan implemented during the third quarter and lower spending on SP-2577. The acquisition of SP-3164 technology for $2.0 million occurred in 2022 did not repeat in 2023.

	SP - 3164		SP- 2577	
Research and development costs by candidates and by categories:	**2023**	**2022**	**2023**	**2022**
Outsourced research and development costs	**$ 2,662,072**	**$ 3,832,805**	**$ 1,342,878**	**$ 4,797,053**
Employee-related costs	**263,302**	**182,109**	**1,568,402**	**2,157,338**
Manufacturing and laboratory costs	**1,203,934**	**2,170,682**	**133,159**	**708,941**
Purchased in process research and development costs	**—**	**1,987,900**	**—**	**—**
Total research and development costs	**$ 4,129,308**	**$ 8,173,496**	**$ 3,044,439**	**$ 7,663,332**

General and Administrative Expense

General and administrative expenses were $5.7 million for the year ended December 31, 2023 compared to $7.1 million for the year ended December 31, 2022, the decrease is mainly driven by lower personnel costs, public company expenses and D&O insurance cost.

Liquidity and Capital Resources

Overview

Since inception, we have incurred operating losses and we anticipate that we will continue to incur losses for the foreseeable future. Salarius has spent, and if the merger with Decoy is not consummated, expects to continue to spend, substantial amounts in connection with implementing its business strategy, including its planned product development efforts, its clinical trials and its research and development efforts. If the merger is not consummated, Salarius will need to attempt to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop its drug candidates.

As of September 30, 2024, cash and cash equivalents totaled $3.3 million, which were held in bank deposit accounts and a money market account. Working capital totaled $2.9 million as of September 30, 2024. Our cash and cash equivalents balance decreased during the nine months ended September 30, 2024, primarily due to cash used in operating activities. We believe that our $3.3 million in cash and cash equivalents on hand as of September 30, 2024 is sufficient to fund our current and restructured operations into the first half of 2025. Our stockholders' equity balance was $2.9 million at September 30, 2024.

To provide the maximum degree of financial flexibility, and subject to the closing of the Merger, we may consider various potential opportunities to fund future operations and/or modulate liquidity needs, including: (i) seeking various strategic transactions, including a merger, licensing arrangement or sale that provide funding for our programs; (ii) entering into one or more collaborations to offset costs; (iii) reducing our expenditures on all business activities and/or restructuring our operations and reducing staff. If we are unable to execute on these activities, we may be forced to evaluate additional alternatives including a wind down of our operations.

We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize our product candidate. At the same time, in connection with the transactions contemplated by the Merger Agreement, we expect to continue to incur significant expenses and expect that our operating losses may fluctuate significantly from quarter-to-quarter and year-to-year.

To date, we have secured capital from the sale of equity and grant revenue. Until we can generate a sufficient amount of revenue from our products, if ever, we intend, when required, to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments. We may also consider new collaborations or selectively partnering our technology. However, we cannot provide any assurance that we will be successful in accomplishing any of our plans to obtain additional capital or be able to do so on favorable terms acceptable to us. If we are unable to obtain additional financing, we may be required to significantly delay, scale

back or discontinue the development or commercialization of our product candidate. Furthermore, we may be unable to complete a collaboration, or if we do, we may be forced to relinquish valuable future product rights.

Although we have entered into the Merger Agreement, the Merger may never be consummated or may not close prior to our cash position getting to the point that we will need to pursue the winding down and dissolution of Salarius. If we do not raise capital or consummate the Merger in the next several months, we will be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection or engage in a similar process.

Cash Flows

	Nine months ended September 30,	
	2024	2023
Net cash (used in) provided by in:		
Operating activities	$ (3,782,819)	$ (11,334,908)
Financing activities	1,166,938	6,809,061
Net decrease in cash and cash equivalents	$ (2,615,881)	$ (4,525,847)

	Year Ended December 31	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (12,846,137)	$ (17,595,321)
Investing activities	—	$ (1,500,000)
Financing activities	6,639,612	$ 1,987,376
Net increase (decrease) in cash and cash equivalents	$ (6,206,525)	$ (17,107,945)

	Year Ended December 31	
	2023	2022
Net proceeds from issuance of equity securities	$ 6,920,529	$ 1,987,376
Payments on note payable	$ (280,917)	
Net cash provided by financing activities	**$ 6,639,612**	**$ 1,987,376**

Operating Activities

Net cash used in operating activities was $3.8 million for the nine months ended September 30, 2024, a decrease of approximately $7.6 million from the nine months ended September 30, 2023. The decrease is primarily due to significantly reduced operating expenses and a significant reduction of accounts payable balance during the current period compared to the same period last year.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was $1.2 million, mainly resulting from Salarius' sale of common shares under the ATM program offset by the repayments on notes payable for D&O insurance. Net cash provided by financing activities for the nine months ended September 30, 2023 was $6.8 million, resulting from Salarius' sale of common shares under its ATM offering and Purchase Agreement.

During the twelve months ended December 31, 2023, Salarius received $1.4 million of cash from Cancer Prevention and Research Institute of Texas. As of December 31, 2023, Salarius had $5.2 million of working capital and our cash and cash equivalents totaled $5.9 million, which were held in bank and money market accounts. Salarius' cash and cash equivalents balance decreased during the year ended December 31, 2023, primarily due to the cash used in operating activities, partially offset by capital received from financing activities.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the condensed consolidated balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our condensed consolidated financial statements prospectively from the date of the change in estimate.

Our significant accounting policies are described in Note 2 to our audited consolidated financial statements for the year ended December 31, 2023 in this prospectus. We believe that our accounting policies relating to research and development expenses, and stock-based compensation are the most critical to understanding and evaluating our reported financial results. We have identified these policies as critical because they both are important to the presentation of our financial condition and results of operations and require Salarius to make judgments and estimates on matters that are inherently uncertain and may change in future periods. For more information regarding these policies, you should refer to Note 2 of our audited consolidated financial statements included in this prospectus.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and does not have any holdings in variable interest entities.

Application of New Accounting Standards

See Note 2 – Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial positions and cash flows.

Capital Resources

We expect to continue to incur additional costs associated with our limited ongoing research and development activities and our continued operation as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we anticipate we will need substantial additional funding in connection with our continuing operations.

We have no products approved for commercial sale, have not generated any revenue from product sales to date and have suffered recurring losses from operations since our inception. The lack of revenue from product sales to date and recurring losses from operations since our inception raise substantial doubt as to our ability to continue as a going concern. Until we can generate a sufficient amount of revenue from our products, if ever, we would expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to consummate the Merger or raise additional capital in sufficient amounts or on terms acceptable to us, we will need to pursue a dissolution and liquidation of our company. Based on our expected cash requirements, we believe that there is substantial doubt that our existing cash and cash equivalents will be sufficient to fund our operation through one year from the date of this report.

Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

- the timing of consummation of the Merger, if such Merger is consummated at all;
- the outcome, timing and cost of regulatory approvals;

- the costs involved in patent filing, if any, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of our product candidates manufactured.

We may finance our future cash needs primarily through the issuance of additional equity and potentially through borrowing, or strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts.

Successful development of product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to continue our operations.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OF DECOY

You should read the following discussion and analysis of financial condition and results of operations of Decoy Therapeutics, Inc. together with our financial statements and the related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

In this sub-section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations of Decoy," unless otherwise specified, references to "company," "we," "us" and "our" are references to Decoy only.

The following table sets forth our results of operations for the year ended December 31, 2023, compared to the year ended December 31, 2022:

	Year ended December 31,		
	2023	2022	Change
Operating Expenses			
General and administrative	$ 1,065,022	$ 1,024,835	$ 40,187
Research and development	2,384,897	2,265,601	119,296
Total operating expenses	$ 3,449,919	$ 3,290,436	159,483
Other (income) and expenses			
Grant income	$ (666,201)	$ (738,990)	72,789
Fair value adjustment to convertible notes	5,643,000	703,000	4,940,000
Warrant liability (income) expense	(251,000)	108,000	(359,000)
Financing expense	52,556	22,500	30,056
Unrealized loss (gain)	—	(315)	315
Interest and financing expense	1,100,265	331,011	769,254
Total other expense	5,878,620	425,206	5,453,414
Net loss	$ (9,328,539)	$ (3,715,643)	$ (5,612,896)

General and Administrative Expenses

General and administrative expenses were approximately $1,065,000 and $1,025,000, in the year ended December 31, 2023 and 2022, respectively, representing an increase of $40,000, or 3.9%. The increase was primarily due to increases in employee compensation of $75,000, travel expenses of $31,000, office supplies of $17,000 and an increase of $45,000 in non-cash stock-based compensation expense, offset by a decrease in legal fees and professional services of $131,000.

Research and Development Expenses

Our research and development expenses during the year ended December 31, 2023 and 2022 were approximately $2,385,000 and $2,266,000, respectively, representing an increase of $119,000, or approximately 5.3%. The increase was primarily due to an increase in employee compensation of $626,000, offset by a decrease of $535,000 worth of expenditures on our development programs. The increase also included approximately $25,000 in non-cash stock-based compensation expense.

Other Expenses:

Grant Income

Our grant income during the year ended December 31, 2023 and 2022 were approximately $666,000 and $739,000, respectively, representing a decrease of $73,000, or approximately 9.9%. The decrease corresponds with the decrease in our research and development expenditures in the year ended December 31, 2023.

Fair Value adjustment to convertible notes payable

We determined our convertible notes issued to investors required liability treatment at fair value, which was remeasured at each reporting period. In the year ended December 31, 2023, we incurred a fair value loss of $5.6 million related to the convertible notes. In the year ended December 31, 2022, we incurred a fair value loss of $703,000 related to the convertible notes.

Warrant liability (income) expense

We determined our warrants issued to investors in our senior secured convertible promissory notes required liability treatment at fair value, which was remeasured at each reporting period. In the year ended December 31, 2023, we incurred a fair value income of $251,000 related to these warrants. In the year ended December 31, 2022, we incurred a fair value expense of ($108,000) related to these warrants.

Interest expense

We had interest expense of approximately $1.1 million and $331,000, in the year ended December 31, 2023 and December 31 2022, respectively, from our financings with convertible debt. The increase in interest expense in the year ending December 31, 2023 is the result of increased debt balances.

Summary Statement of Cash Flows – Year ended December 31, 2023 compared to Year ended December 31, 2022

As of December 31, 2023, we had approximately $4,156,000 in cash and cash equivalents. The table below presents our cash flows for the year ended December 31, 2023 and 2022:

	Year ended December 31,	
	2023	2022
Net cash provided by (used in) operating activities	$ 1,259,921	$ (2,707,565)
Net cash used in investing activities	(8,669)	(158,098)
Net cash provided by financing activities	1,280,939	1,999,835
Net change in cash and cash equivalents	$ 2,532,191	$ (865,828)

Operating Activities

Net cash provided by (used in) operating activities was approximately $1,260,000 and ($2,708,000) for the year ended December 31, 2023 and 2022, respectively. The increase in net cash provided by operating activities in 2023 was primarily due to non-cash increase in fair value and interest expense related to our convertible notes, offset by an increase of deferred revenue from grants for the year ended December 31, 2023.

Investing Activities

Net cash used in investing activities in the year ended December 31, 2023 was approximately $9,000 and net cash used in investing activities in the year ended December 31, 2022 was approximately $158,000. The decrease in net cash used is due to a reduction of purchases in property, plant and equipment in 2023.

Financing Activities

Net cash provided by financing activities was approximately $1,281,000 for the year ended December 31, 2023. The net cash provided decreased due to the receipt of approximately $1,281,000 in net proceeds from the notes issued in 2023. Net cash provided by financing activities in the year ended December 31, 2022 was approximately $2,000,000, representing net proceeds of $2,250,000 from notes issued in 2022, offset by repayments of $250,000 in notes during the year ended December 31,2022.

Results of Operations – Nine months ended September 30, 2024 compared to the nine months ended September 30, 2023

The following table sets forth our results of operations for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023:

	Nine months ended September 30,		
	2024	2023	Change
Operating Expenses			
General and administrative	$ 872,415	$ 710,971	$ 161,444
Research and development	1,925,148	1,662,456	262,692
Total operating expenses	$ 2,797,563	$ 2,373,427	$ 424,136
Other (income) and expenses			
Grant income	$ (1,134,817)	$ (307,997)	$ (826,820)
Fair value adjustment to convertible notes	406,000	2,604,000	(2,198,000)
Warrant liability (income) expense	174,465	—	174,465
Financing expense	97,007	28,993	68,014
Unrealized loss (gain)	517	—	517
Interest expense	913,093	1,231,402	(318,309)
Total other expense	456,265	3,556,399	(3,100,134)
Net loss	$ (3,253,828)	$ (5,929,826)	$ 2,675,998

General and Administrative Expenses

General and administrative expenses were approximately $872,000 and $711,000, in the nine months ended September 30, 2024 and 2023, respectively, representing an increase of $161,000, or approximately 22.6%. The increase was primarily due to increases in employee compensation of $10,000, bank and payroll fees of $28,000, office supplies of $26,000 and an increase of $88,000 in non-cash stock-based compensation expense.

Research and Development Expenses

Research and development expenses were approximately $1,925,000 and $1,662,000, in the nine months ended September 30, 2024 and 2023, respectively, representing an increase of $263,000, or approximately 15.8%. The increase was primarily due to an increase in employee compensation of $138,000, and approximately $130,000 in non-cash stock-based compensation expense.

Other (Income) and Expenses:

Grant Income

Our grant income during the nine months ended September 30, 2024 and 2023 were approximately $1,135,000 and $308,000, respectively, representing an increase of $827,000, or approximately 268.5%. The increase is a result of increased activity around the work being done on grant based projects during the nine months ending September 30, 2024.

Fair Value adjustment to convertible notes payable

We determined our convertible notes issued to investors required liability treatment at fair value, which was remeasured at each reporting period. In the nine months ended September 30, 2024, we incurred a fair value expense of $406,000 related to the convertible notes. nine months ended September 30, 2023, we incurred a fair value expense of $2.6 million related to the convertible notes.

Warrant liability (income) expense

We determined our warrants issued to investors in our senior secured convertible promissory notes required liability treatment at fair value, which was remeasured at each reporting period. In the nine months ended September 30, 2024, we incurred a fair value expense of $175,000 related to these warrants. There were no warrants issued in the nine months ended September 30, 2023.

Interest expense

We had interest expense of approximately $913,000 and $1.2 million, in the nine months ended September 30, 2024 and 2023, respectively, from our financings with convertible debt.

Liquidity and Capital Resources

We have incurred net losses every year since inception and had an accumulated deficit of approximately $18.3 million at September 30, 2024. We have a limited operating history and have historically funded our operations through debt and equity financings. We incurred net losses of approximately $3.3 million and negative cash flows from operations of $1.6 million for the nine months ended September 30, 2024. At September 30, 2024, we had cash and cash equivalent balances totaling $3.2 million. We have determined that we do not have sufficient resources to effect our business plan for at least one year from the issuance of the unaudited consolidated financial statements included in this prospectus. We are subject to risks common to development stage biopharmaceutical companies including, but not limited to, unanticipated development costs and the ability to estimate such occurrences, if any, on our cash, liquidity, additional financing requirements, and availability. Accordingly, we need to raise additional funds. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of planned clinical trials and our expenditures on other research and development activities.

Future Funding Requirements

We will need to obtain further funding through public or private offerings of our capital stock, debt financing, collaboration and licensing arrangements or other sources, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug development efforts, preclinical development activities, the timing of laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;

- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems; and

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of any future product candidate, or potentially discontinue operations.

To the extent that we raise additional capital through the sale of our equity or convertible debt securities, and pursuant to the exercise of the warrants issued to investors, the ownership interest of our equity holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or proposed products, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market any future product that we would otherwise prefer to develop and market ourselves.

Summary Statement of Cash Flows

As of September 30, 2024, we had approximately $3.2 million in cash and cash equivalents. The table below presents our cash flows for the nine month periods ended September 30, 2024 and 2023:

	Nine moths ended September 30,	
	2023	**2022**
Net cash provided by (used in) operating activities	$ (1,613,304)	$ 1,725,428
Net cash used in investing activities	—	(4,473)
Net cash provided by financing activities	655,555	666,324
Net change in cash and cash equivalents	$ (957,749)	$ 2,387,278

Operating Activities

Net cash (used in) provided by operating activities was approximately ($1,613,000) and $1,725,000 in the nine months ended September 30, 2024 and 2023, respectively. The decrease in the nine months ended September 30, 2024 was mostly due to decreases in decrease in deferred revenue and decreases in non-cash expense adjustments to fair value and interest expense related to our convertible notes.

Investing Activities

Net cash used in investing activities was approximately $0 and ($5,000) in the nine months ended September 30, 2024 and 2023, respectively, consisting of purchases in property, plant and equipment in the nine month period ended September 30, 2023.

Financing Activities

Net cash provided by financing activities was approximately $656,000 for the nine months ended September 30, 2024, consisting of the receipt of approximately $538,000 in net proceeds from notes and $118,000 in due to proceeds from officers of Decoy. Net cash provided by financing activities was approximately $666,000 for the nine months ended September 30, 2023, consisting of the receipt of $666,000 in net proceeds from the issuance of notes.

SALARIUS MANAGEMENT

Directors

Salarius' board of directors consists of seven (7) directors which are divided into three classes: Class I, Class II, and Class III. Each class has a three-year term:

- Class I directors are Arnold C. Hanish and William K. McVicar and their terms will expire at the annual meeting of stockholders to be held in 2025.
- Class II directors are David J. Arthur, Bruce J. McCreedy, and Jonathan Lieber and their terms will expire at the annual meeting of stockholders to be held in 2026.
- Class III directors are Tess Burleson and Paul Lammers and their terms will expire at the annual meeting of stockholders to be held in 2027.

The following table sets forth the name, age and committee appointments of each of Salarius' current directors as of January 14, 2025:

Name	Age	Position
David J. Arthur	62	President, Chief Executive Officer and Director
William K. McVicar	67	Chair
Tess Burleson[(1)(2)(3)]	57	Director
Arnold C. Hanish[(1)(3)]	77	Director
Paul Lammers[(3)]	67	Director
Jonathan Lieber[(1)(2)]	55	Director
Bruce J. McCreedy[(2)]	65	Director

(1) Member of the Audit Committee.
(2) Member of the Nominating and Corporate Governance Committee.
(3) Member of the Compensation Committee.

The names of the nominees and certain biographical information about each current director, including a description of his or her business experience, qualifications, education and skills that led Salarius' board of directors to conclude that such individual should serve as a member of Salarius' board of directors, are set forth below:

Class I Directors

Arnold Hanish

Mr. Hanish has served as a member of the Salarius board of directors since July 2019. Mr. Hanish served in various management roles at Eli Lilly and Company, a pharmaceutical company, including Vice President and Chief Accounting Officer. Prior to Eli Lilly and Company, Mr. Hanish held numerous positions at Arthur Young & Company (currently Ernst & Young) from 1970-1984, including being the Director of Tax in the Indianapolis office from 1979-1984. Mr. Hanish served as a member of the Deloitte and Touche, LLP, a professional services company, Audit Quality Review Council from 2013 to 2023. In addition, Since September 2012, Mr. Hanish has served on the board of directors of Omeros Corporation (Nasdaq:OMER), a biopharmaceutical company, and Chairs its Audit Committee. From 2007 to 2010, Mr. Hanish served as the Chairperson of the Financial Executives International Committee on Corporate Reporting and was on their SEC and Public Company Accounting Oversight Board ("PCAOB") subcommittees. In 2016, Mr. Hanish was inducted into the Financial Executives International Hall of Fame. From 2004 to 2008 and again in 2011 and 2012, Mr. Hanish was a member of the Standing Advisory Group of the PCAOB, a nonprofit audit oversight organization. Since 2010, Mr. Hanish has served on the Dean of the College of Businesses, Business Advisory Council and recently received the Distinguished Service Award from the college of business at the University of Cincinnati. Mr. Hanish earned a B.B.A. in Accounting from the University of Cincinnati and is a licensed CPA in Indiana and Ohio.

Salarius' board of directors believes that Mr. Hanish is qualified to serve on the Salarius board of directors as a result of his experience in the pharmaceutical industry, as well as deep experience in accounting and public company financial matters.

William McVicar, Ph.D.

Dr. McVicar has served as a member of the Salarius board of directors since the completion of the reverse acquisition in July 2019. Prior to completion of the acquisition, Dr. McVicar served as a member of the board of directors of Flex Pharma, Inc. ("Flex Pharma") since August 2017, and served as its chief executive officer from July 2017 to July 2019. Dr. McVicar joined Flex Pharma in April 2017 as President of Research & Development. Prior to joining Flex Pharma, Dr. McVicar also serves as president and CEO of Neuromity Therapeutics, LLC since November 2021 and serves as Chief Operating Officer (acting) at Satellos Biosciences, Inc. since July 2020. Additionally, Dr. McVicar served as Executive Vice President of pharmaceutical development, chief scientific officer and president during his tenure at Inotek Pharmaceuticals Corporation from September 2007 to April 2017. Dr. McVicar also held various positions at Sepracor, Inc, Novartis AG and RPR Gencell, the Gene and Cell Therapy Division of Rhone Poulenc Rorer. Dr. McVicar earned his B.S. in Chemistry from the State University of New York College at Oneonta and his Ph.D. in Chemistry from the University of Vermont.

Salarius' board of directors believes that Dr. McVicar is qualified to sit on the Salarius board of directors due to his over 30 years of biologic and drug development experience and his experience as a senior executive.

Class II Directors

David J. Arthur

Mr. Arthur has served as Salarius' President and Chief Executive Officer and a director since July 2019 and as the Chief Executive Officer of Salarius' predecessor since November 2015 and as a manager of Salarius' predecessor's board of managers since January 2017. Mr. Arthur's full-time employment with Salarius ended, effective February 2024, but he continues to serve as Chief Executive Officer of Salarius in his role as a part-time consultant. From January 2012 to October 2015, Mr. Arthur served as managing director of Dacon Pharma, LLC, a life science focused strategy, planning and evaluation company. From 1990 to 2010, Mr. Arthur served in a number of executive roles at Eli Lilly and Company and from 2010 to 2011 served in executive roles with Boehringer Ingelheim GmbH. Mr. Arthur earned a B.S. in Chemical Engineering from North Carolina State University and an M.B.A. from the Duke University Fuqua School of Business.

Salarius' board of directors believes that Mr. Arthur's experience as Salarius' Chief Executive Officer, and his past experience as a life sciences executive and as a committee chairman and member on the executive committees of a variety of major pharmaceutical alliances, including Eli Lilly/BioMS, Eli Lilly/Amylin and Boehringer Ingelheim/Eli Lilly qualify him to serve on Salarius' board of directors.

Jonathan Lieber

Mr. Lieber has served as a member of the Salarius board of directors since June 2020. Since February 2023, he has served as Chief Financial Officer and Treasurer of Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases. From September 2021 until its sale in November 2022, he served as Chief Financial Officer of Applied Genetic Technologies Corporation (Nasdaq: AGTC), a clinical stage biotechnology company focused on the development and commercialization of adeno-associated virus (AAV)-based gene therapies for the treatment of rare and debilitating diseases. From December 2018 through September 2021, Mr. Lieber served as a Managing Director of Danforth Advisors LLC, a firm that provides strategic CFO advisory and outsourced accounting services to healthcare companies. In that capacity, he served as interim CFO for several private and public healthcare companies. From July 2015 through September 2019, Mr. Lieber was Chief Financial Officer of Histogenics Corporation (Nasdaq: HSGX) a cell therapy company developing products for the orthopedics market. Mr. Lieber received an M.B.A. in finance from the Stern School of Business of New York University and a B.S. in business administration from Boston University.

Salarius' board of directors believes that Mr. Lieber is qualified to serve on the Salarius board of directors due to his experience in the healthcare industry, which will enable him to contribute important strategic insights to Salarius.

Bruce J. McCreedy, Ph.D.

Dr. McCreedy has served as a member the Salarius board of directors since July 2019 and has served as Chief Scientific Officer of ONK Therapeutics, Inc. effective December 1, 2022. Prior to that, Dr. McCreedy served as the Chief Scientific Officer of Myeloid Therapeutics, Inc. from April of 2021 until November, 2022. Dr. McCreedy served as Salarius' interim Chief Science Officer from January 2020 through March 30, 2021 and was the Senior Vice President of Cell Therapy at Precision Biosciences, Inc. from 2015 to 2020. Prior to his position at Precision Biosciences, Dr. McCreedy served as the Executive Vice President of Research and Development and Chief Development Officer of Neximmune, Inc., a biotechnology company, from April 2011 to August 2015, and the Managing Partner of PharmaNav, LLC, a biotechnology company, from 2008 to 2011. From 2006 to 2008, Dr. McCreedy served as Vice President of Strategic and Clinical Development at Metabolon, Inc., a metabolomics company and from 2002 to 2006 served as the President, Chief Executive Officer and a Director for Fulcrum Pharma Developments, Inc., a drug development company (acquired by Icon plc). Prior to 2002, Dr. McCreedy has also served as Vice President at Triangle Pharmaceuticals, Inc., a pharmaceutical company (acquired by Gilead Sciences, Inc.), CEO of Therapyedge, Inc., a healthcare and information services company (acquired by Advanced Biological Laboratories S.A.), and Associate Vice President of Laboratory Corporation of America Holdings, a clinical laboratory network, and Roche Biomedical Laboratories, Inc., a drug development company. Dr. McCreedy earned a B.S. in Medical Microbiology from Wake Forest University and a Ph.D. in Microbiology and Immunology from Wake Forest University School of Medicine.

Salarius' board of directors believes that Dr. McCreedy is qualified to serve on the Salarius board of directors due to deep experience in the biotechnology industry, which will enable him to contribute important strategic insights to Salarius.

Class III Directors

Tess Burleson

Ms. Burleson has served as a member of the Salarius board of directors since July 2019. Ms. Burleson has served as the chief operating officer of TGen, a Medical R&D organization, since 2007, and has served as the president of TGen Health Ventures, LLC a venture capital company, since 2009. She also serves as an advisor to bankers and investors in the life sciences industry. Prior to joining TGen, Ms. Burleson served as the chief financial officer at Lovelace Health System enterprises from 1997 to 2007, president at Lovelace Scientific Resources from 1993 to 1997, and as a senior associate at KPMG from 1990 to 1993. Ms. Burleson earned a B.B.A from Robert O. Anderson School of Business at University of New Mexico and her M.B.A. from the Anderson Graduate School of Management at University of New Mexico.

Salarius' board of directors believes that Ms. Burleson is qualified to serve on the Salarius board of directors as a result of her extensive operational experience in the biotechnology industry and experience in financial and accounting matters.

Paul Lammers, MD, MSc

Dr. Lammers has served as a member of the Salarius board of directors since July 2019 and previously served as Salarius' lead independent director. In February 2024, Dr. Lammers retired as CEO of Triumvira Immunologics, a privately held engineered T cell therapy company and for which he raised over $125 million from leading venture firms, where he served starting in 2018. Before Triumvira, Dr. Lammers served as President & CEO at Mirna Therapeutics, for which company he raised $160 million through venture capital and Federal and State government funding, as well as a public listing (Nasdaq: MRNA) in 2015. Previously, he served as Chief Medical Officer and Head of US Product Development for EMD Serono. During his early industry tenure, Dr. Lammers also held various executive/senior management positions in clinical development, medical and regulatory affairs, at different pharmaceutical companies, as well as at small public and privately held biotechnology companies. Dr. Lammers

serves as Director for private oncology biotechnology company, Immunomet Therapeutics, and private oncology biotechnology company, Diakonos Oncology. Dr. Lammers obtained both his Master of Science in Biology, and his Medical Degree from Radboud University, Nijmegen, The Netherlands.

Salarius' board of directors believes that Dr. Lammers is qualified to serve on the Salarius board of directors as a result of his extensive experience in the pharmaceutical industry and deep understanding of oncology drugs.

Executive Officers

The following table shows information about Salarius' executive officers as of January 14, 2025:

Name	Age	Position
David J. Arthur	62	President, Chief Executive Officer and Director
Mark J. Rosenblum	71	Executive Vice President of Finance and Chief Financial Officer

The following presents biographical information for each of Salarius' executive officers in the table above, other than for Mr. Arthur, whose information is presented above.

Mark J. Rosenblum. Mr. Rosenblum has served as Salarius' Executive Vice President Finance and Chief Financial Officer since September 2019. Prior to September 2019, Mr. Rosenblum served as a financial consultant to Salarius since February 2019. Prior to joining Salarius, Mr. Rosenblum served as chairman, chief executive officer and a director of ActiveCare, Inc. (Nasdaq: ACAR), a healthcare company, from December 2017 to March 2019, which was sold to Biotelemetry, Inc (now Royal Philips (NYSE: PHG). Mr. Rosenblum worked as a financial consultant for various companies from 2014 to 2017. Prior to that, Mr. Rosenblum served as the chief financial officer of Advaxis, Inc. (Nasdaq: ADXS), a biotechnology company, from January 2010 to April 2014. From 1985 through 2003, Mr. Rosenblum was employed by Wellman, Inc., a global public chemical manufacturer, which was subsequently acquired by DAK Americas, serving in various capacities including chief accounting officer. Mr. Rosenblum holds both a Masters in Accountancy and a B.S. degree in Accounting from the University of South Carolina. Mr. Rosenblum began his career in 1977 with Haskins & Sells, CPA (currently known as Deloitte), was a licensed Certified Public Accountant for over 30 years, and is currently a member of the American Institute of Certified Public Accountants.

Family Relationships

There are no family relationships among any of Salarius' directors or executive officers.

Arrangements between Officers and Directors

To Salarius' knowledge, there is no arrangement or understanding between any of Salarius' officers and any other person, including directors, pursuant to which the officer was selected to serve as an officer.

Corporate Governance

Board of Directors

Salarius' business and affairs are organized under the direction of the Salarius board of directors, which currently consists of seven members. Dr. McVicar currently serves as the Chair of Salarius' board of directors. The primary responsibilities of Salarius' board of directors are to provide oversight, strategic guidance, counseling, and direction to Salarius' management. Salarius' board of directors meets on a regular basis and additionally as required.

Director Independence

The Nasdaq Listing Rules generally require that a majority of the members of a listed company's board of directors must qualify as "independent" as affirmatively determined by its board of directors. The Salarius board of directors consults with Salarius' counsel to ensure that the Salarius board of directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Salarius' board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director and director nominee. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, Salarius' board of directors has determined that six of Salarius' current directors, including Mr. McVicar, Ms. Burleson, Mr. Hanish, Dr. Lammers, Dr. McCreedy and Mr. Lieber, are "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements of Nasdaq.

Salarius' board of directors has determined that Mr. Arthur, Chief Executive Officer of Salarius in his role as a part-time consultant, is not independent under the applicable rules and regulations of the SEC and Nasdaq Listing Rules. In making these determinations, Salarius' board of directors considered the current and prior relationships that each non-employee director has with Salarius and all other facts and circumstances Salarius' board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

DECOY MANAGEMENT

Current Directors, Executives and Employees of Decoy

Currently Decoy's executives include its co-founders, who are highly experienced senior scientists, clinicians, biotechnology and pharmaceutical executives, and a renowned professor of peptide chemistry from the Massachusetts Institute of Technology ("MIT"):

- Rick Pierce, Chief Executive Officer and Director, a serial biotech entrepreneur who has helped build a number of biotechnology companies over the last 25 years, including Javelin Pharmaceuticals, which was sold to Pfizer, which now markets its lead drug, Dyloject.
- Barbara Hibner Ph.D., Chief Scientific Officer and Director, with over 25 years of experience in pharmacology and drug discovery and development in pharmaceutical and biotechnology companies resulting in contributions to 2 oncology drugs sorafenib and ixazomib.
- Peter Marschel, MS MBA, Chief Business Officer & Director with over fifteen years of experience in business development, financial and commercial roles and large pharmaceutical and biotechnology companies, including leading market analytics for the cystic fibrosis franchise at Vertex Pharmaceuticals.
- Michael Lipp, Ph.D. Chief Technology Officer with over two decades of experience in pharmaceutical development and drug delivery technologies ranging from the preclinical stage through commercial approval.
- Bradley L. Pentelute, Ph.D., Professor of Chemistry at MIT and co-founder, whose lab invented the world's fastest peptide synthesizer and has advised large pharmaceutical and biotechnology companies on advancing their peptide drug discovery and manufacturing efforts.
- Shahin Gharakhanian, MD, SAB chair and acting-Chief Medical Officer, is a Physician-Executive with expertise in pharmaceutical medicine, leadership and management, and an international track record and former Vice President within the Medicines Development Group, Global R&D at Vertex Pharmaceuticals with 2 antiviral drugs taken successfully to commercialization.

Decoy currently has eight full time employees and seven dedicated consultants, responsible for preclinical, toxicology, clinical development, prescriber, payor, market access and pricing strategy, chemistry, manufacturing, and control, quality, and regulatory strategy and execution, finance strategy and business development. Decoy also has three highly engaged members of its Scientific Advisory Board: Dr. Mark Garnick, who has served for 15 years as a member of an FDA oncologic Drugs Advisory Committee and is an expert in oncology. Dr. Daniel Kuritkes, Chief of Infectious Disease at Brigham and Women's Hospital, and Yonatan Grad, Epidemiologist and Professor of Immunology and Infectious Disease at Harvard T.H. Chan School of Public Health.

Decoy's employees and advisors have significant industry experience and have been involved in the discovery, development, regulatory approvals and commercial launches of several successful drugs.

MANAGEMENT FOLLOWING THE MERGER

Management Following the Merger

The following table lists names, ages and positions of the individuals who are expected to serve as executive officers and directors of the combined company following completion of the Merger. In addition to Mr. Pierce and Ms. Hibner, following stockholder approval of conversion of the preferred stock to be issued upon completion of the Merger, additional non-employee directors will be designated by Decoy.

Name	Age	Position
Executive Officers		
Frederick E. Pierce	63	Chief Executive Officer and Director
Mark Rosenblum	71	Chief Financial Officer
Peter Marschel	50	Chief Business Officer
Barbara Hibner	63	Chief Scientific Officer and Director

The following presents biographical information for each of the combined company's executive officers in the table above.

Frederick E. Pierce. Mr. Pierce has been Decoy's Chief Executive Officer and director since he co-founded it in 2020. From September 2022 until November 2024, Mr. Pierce served as an executive officer of Innovation1 Biotech, Inc., a drug discovery company. Mr. Pierce is also an advisor to the Canadian Consulate of Boston/Cambridge's Healthcare and Technology Accelerator and a Board member of the Canadian Entrepreneurs of New England, where he is Chairman of the Life Sciences Leadership Council. From 2017 through 2020, Mr. Pierce served as a Senior Advisor for Bionest Partners, a life sciences consulting company. Mr. Pierce is a serial biotech entrepreneur with over 20 years of increasing senior leadership and operating experience building successful biotechnology companies.

Mark J. Rosenblum. Mr. Rosenblum has served as Salarius' Executive Vice President Finance and Chief Financial Officer since September 2019. Prior to September 2019, Mr. Rosenblum served as a financial consultant to Salarius since February 2019. Prior to joining Salarius, Mr. Rosenblum served as chairman, chief executive officer and a director of ActiveCare, Inc. (Nasdaq: ACAR), a healthcare company, from December 2017 to March 2019, which was sold to Biotelemetry, Inc. (now Royal Philips (NYSE: PHG). Mr. Rosenblum worked as a financial consultant for various companies from 2014 to 2017. Prior to that, Mr. Rosenblum served as the chief financial officer of Advaxis, Inc. (Nasdaq: ADXS), a biotechnology company, from January 2010 to April 2014. From 1985 through 2003, Mr. Rosenblum was employed by Wellman, Inc., a global public chemical manufacturer, which was subsequently acquired by DAK Americas, serving in various capacities including chief accounting officer. Mr. Rosenblum holds both a Masters in Accountancy and a B.S. degree in Accounting from the University of South Carolina. Mr. Rosenblum began his career in 1977 with Haskins & Sells, CPA (currently known as Deloitte), was a licensed Certified Public Accountant for over 30 years, and is currently a member of the American Institute of Certified Public Accountants.

Peter Marschel. Mr. Marschel, MSA MBA has been Decoy's Chief Business Officer and director since he co-founded it in 2020. Until April 2020 Mr. Marschel was co-founder and Chief Financial Officer of PercepTx, a targeted cancer immunotherapy accelerator focused on using computational modeling and quantitative pharmacology to rapidly increase the value of preclinical monoclonal antibody-based therapeutic assets. Prior to that he served in a range of business development, analytics, and commercial roles at Merck, Vertex Pharmaceuticals, and Takeda Pharmaceuticals, including leading market analytics for the cystic fibrosis franchise at Vertex Pharmaceuticals.

Barbara Hibner. Dr. Hibner, Ph.D has been Decoy's Chief Scientific Officer, Director and Board Chair since she co-founded the company in 2020. From January 2017 to April 2020 Dr. Hibner was co-founder and Chief Executive Officer of PercepTx, a targeted cancer immunotherapy company focused on using computational modeling and quantitative pharmacology to discover and develop novel antibody drug conjugates. Prior to that she

served in a range of scientific and managerial positions in discovery, pharmacology and research quality roles in Bayer Pharmaceuticals, Chiron, Millennium and Takeda Pharmaceuticals. Dr. Hibner's work has contributed to the approval of two small molecule drugs, sorafenib and ixazomib.

Family Relationships

There are no family relationships among the combined company's directors or executive officers.

SALARIUS EXECUTIVE COMPENSATION

Salarius' "named executive officers" for the year ended December 31, 2024, were:

- David J. Arthur, Salarius' President and Chief Executive Officer; and
- Mark J. Rosenblum, Salarius' Executive Vice President of Finance and Chief Financial Officer.

On February 20, 2024, Salarius entered into a separation and release agreement with Mr. Arthur, as more fully described below in "Employment and Separation Agreements."

On February 20, 2024, Salarius and Mr. Rosenblum, entered into that certain Amendment to Executive Employment Agreement, which amends that certain Executive Employment Agreement, dated April 24, 2020, by and between Salarius and Mr. Rosenblum solely to provide Mr. Rosenblum with the option to receive any severance that may be owed to Mr. Rosenblum pursuant to Section 5I(i) thereof in in equal installments over a period of time or in a lump-sum amount.

Investors are encouraged to read the compensation discussion below under "Narrative Disclosure to Summary Compensation Table" in conjunction with the summary compensation tables and related notes.

Summary Compensation Table

The following table sets forth compensation for services rendered in all capacities to Salarius for the years ended December 31, 2024 and 2023 for Salarius' named executive officers.

Name and Principal Position	Year	Salary	Stock Awards [2]	Option Awards [3]	All Other Compensation	Total
David J. Arthur *President and Chief Executive Officer*	**2024**	$ 176,153 [1]	—	$ 8,265	$ 550,032 [4]	$ 734,450
	2023	$ 500,000	$ 31,400	—	$ 13,200 [5]	$ 544,600
Mark J. Rosenblum *Executive Vice President, Finance and Chief Financial Officer*	**2024**	$ 330,000	—	$ 11,372	$ 9,050 [5]	$ 350,422
	2023	$ 330,000	$ 12,560	—	$ 13,200 [5]	$ 355,760

(1) The amount shown comprises $68,750 in salary earned and paid in 2024 to Mr. Arthur pursuant to his employment agreement and $107,403 in consulting fees earned and paid to him pursuant to that certain Consulting Agreement. dated February 20, 2024, by and between Salarius and Mr. Arthur.

(2) The amounts reported in this column represent the grant date fair value of the restricted stock granted, calculated in accordance with FASB ASC Topic 718 using the close price of Salarius' common stock on the grant date.

(3) The amounts reported in this column represent the grant date fair value of stock options using the Black-Scholes option-pricing model computed in accordance with FASB ASC Topic 718. See Note 8 to Salarius' financial statements contained in its Annual Report on Form 10-K for the year ended December 31, 2023, for the assumptions used in such valuation.

(4) The amount shown represents Mr. Arthur's severance payment of $500,000, unused paid time off of $5,341 and COBRA premiums of $19,691 paid in 2024 pursuant to that certain Separation and Release Agreement, dated February 20, 2024, between Salarius and Mr. Arthur, $2,500 in matching contributions by Salarius pursuant to its 401(k) plan, and $22,500 of director fee earned in 2024 following Mr. Arthur's termination of employment.

(5) The amount shown represents matching contributions by Salarius pursuant to its 401(k) plan.

Narrative Disclosure to Summary Compensation Table

In the process of determining compensation for Salarius' named executive officers, the Compensation Committee considers the current financial position of Salarius, the strategic goals of Salarius, and the performance of each of Salarius' named executive officers. In addition, from time to time, the Compensation Committee considers the various components (described below) of Salarius' compensation program for executives in relation to compensation paid by other public companies, compensation data, their historical review of all executive officer compensation, and recommendations from Salarius Chief Executive Officer (other than for his own salary). The Compensation Committee has the sole authority to select, compensate and terminate its external advisors.

The Compensation Committee utilizes the following components of compensation (described further below) to strike an appropriate balance between promoting sustainable and excellent performance and discouraging any excessive risk-taking behavior:

- Base Salary;
- Non-equity incentive plan compensation;
- Annual long-term equity compensation;
- Personal benefits and perquisites; and
- Acceleration and severance agreements tied to changes in control of Salarius.

Base Salaries

Salarius' named executive officers receive base salaries as set forth in their respective employment or consulting agreements. Each named executive officer is eligible for annual raises subject to review and approval of the Compensation Committee. There were no salary raises in 2024. Mr. Arthur's base salary was $500,000 for the portion of 2024 during which he served as an employee and, following his termination, Mr. Arthur received $10,417 per month pursuant to the terms of his consulting agreement. Mr. Rosenblum's base salary was $330,000 for 2024.

Non-Equity Incentive Plan Compensation

Target bonuses are reviewed annually and established as a percentage of the executives' base salaries, generally based upon seniority of the officer and targeted at or near the median of the peer group (with reference to Salarius' corporate compensation philosophy) and relevant survey data. Each year, the Compensation Committee establishes corporate and individual objectives and respective target percentages, taking into account recommendations from Salarius' Chief Executive Officer as it relates to executive positions other than the Chief Executive Officer's compensation. Salarius' Chief Executive Officer's target bonus is set by the Compensation Committee to align entirely with Salarius' overall corporate objectives. At the end of each fiscal year-end, Salarius' Chief Executive Officer provides the Compensation Committee with a written evaluation showing actual performance as compared to corporate and/or individual objectives, and the Compensation Committee uses that information, along with the overall corporate performance, to determine what percentage of each executive's bonus target will be paid out as a bonus for that year. Overall, the Compensation Committee seeks to establish the corporate and individual functional goals to be highly challenging yet attainable.

Mr. Arthur's and Mr. Rosenblum's target bonus' for both 2024 and 2023 as a percentage of base salary was 50% and 35% respectively. Neither named executive officer received a bonus for Salarius' 2023 and 2024 fiscal years.

Long-Term Equity Compensation

Salarius designed its long-term equity grant program to further align the interests of its executives with those of its stockholders and to reward the executives' longer-term performance. Historically, the Compensation Committee has granted stock options, although from time-to-time, to further increase the emphasis on compensation tied to performance, the Compensation Committee may grant other equity awards as allowed by the Salarius Pharmaceuticals 2015 Equity Incentive Plan. The Compensation Committee may grant stock options, restricted stock, restricted stock units and similar equity awards permitted under Salarius' plans based on its judgment as to whether the complete compensation packages to Salarius' executives, including prior equity awards, are appropriate and sufficient to retain and incentivize the executives and whether the grants balance long-term versus short-term compensation. The Compensation Committee also considers Salarius' overall performance as well as the individual performance of each of Salarius' named executive officers, the potential dilutive effect of restricted stock awards, the dilutive and overhang effect of the equity awards, and recommendations from the Chief Executive Officer (other than with respect to his own equity awards).

Stock options are granted with an exercise price equal to the fair market value of Salarius' common stock on the date of grant.

Restricted stock is granted at the closing price of Salarius' common stock on the grant date.

On February 20, 2024, the Compensation Committee granted Mr. Rosenblum an option to purchase 2,813 shares of Salarius common stock at an exercise price of $4.5688 per share. 25% of the options vests on February 20, 2025 and the remaining 1/36 of the remaining option vests on each monthly anniversary thereafter for 36 months.

On April 11, 2024, the Compensation Committee granted Mr. Arthur an option to purchase 2,563 shares of Salarius common stock at an exercise price of $4.08 per share. 100% of the option vest on April 11, 2025.

Personal Benefits and Perquisites

All of Salarius' executives are eligible to participate in Salarius' employee benefit plans, including medical, dental, vision, life insurance, short-term and long-term disability insurance, flexible spending accounts, 401(k), and an employee stock purchase program. These plans are available to all full-time employees. In keeping with Salarius' philosophy to provide total compensation that is competitive within Salarius' industry, Salarius offers limited personal benefits and perquisites to its executive officers. You can find more information on the amounts paid for these perquisites to or on behalf of Salarius' named executive officers in Salarius' Summary Compensation Table.

Nonqualified Deferred Compensation

None of Salarius' named executive officers participates in or has account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by Salarius. Salarius' board of directors may elect to provide its officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in Salarius' best interests.

Outstanding Equity Awards at fiscal year end

The following table presents certain information concerning equity awards held by Salarius' named executive officers as of December 31, 2024:

	Option Awards					Stock Awards	
Name	Grant Date	Number of securities underlying unexercised options that are exercisable	Number of securities underlying unexercised options that are unexercisable	Option exercise Price	Option expiration date	Number of shares or units of stock that have not vested[3]	Market value of shares or units of stock that have not vested[4]
David J. Arthur	9/10/2019	150	—	$ 1,600	9/10/2029		
	3/23/2020	300	—	$ 122	3/22/2030		
	7/14/2020	1,697	—	$ 264	7/13/2030		
	12/2/2020	1,375	—	$ 148	12/1/2030		
	1/20/2022	1,822	678 [1]	$ 96	1/19/2032		
	1/3/2023					1,302	$ 2,396
	4/11/2024	—	2,563 [2]	$ 4.08	4/11/2034		
Mark J. Rosenblum	9/10/2019	95	—	$ 1,600	9/10/2029		
	3/23/2020	150	—	$ 122	3/22/2030		
	7/14/2020	249	—	$ 264	7/13/2030		
	12/2/2020	400	—	$ 148	12/1/2030		
	1/20/2022	729	271 [1]	$ 96	1/19/2032		
	1/3/2023					521	$ 959
	2/20/2024	—	2,813 [1]	$ 4.57	2/20/2034		

(1) Represents options of which 25% will become exercisable on the one-year anniversary with the remainder becoming exercisable in equal 1/36th installments on the last day of each calendar month thereafter.
(2) 100% of the options will become exercisable on the one-year anniversary of the grant date.
(3) 25% of the shares of restricted stock vested on January 2, 2024 and 1/36 of the remaining shares of restricted stock will vest on monthly anniversaries thereafter.
(4) The market value of unvested stock awards is based on the closing market price of Salarius' common stock on December 31, 2024 of $1.84.

Employment and Separation Agreements

Below are descriptions of the employment or separation agreements with Salarius' named executive officers. Furthermore, each of Salarius' executive officers has executed a form of Salarius' standard proprietary information and inventions assignment agreement.

David J. Arthur

Separation Agreement

On February 20, 2024 (the "Separation Date"), Salarius entered into a separation and release agreement (the "Separation Agreement") with David J. Arthur, Salarius' President and Chief Executive Officer, which provides for Mr. Arthur's separation of employment, effective as of the Separation Date. Under the Separation Agreement, Salarius paid Mr. Arthur a lump-sum payment equal to the amounts owed to him pursuant to Section 5(c)(ii) of that certain Amended and Restated Employment Agreement. Under the terms of the Separation Agreement, Mr. Arthur elected to receive such amounts in a lump sum.

Mr. Arthur has remained as Salarius' principal executive officer and provide services to Salarius in such capacity pursuant to a Consulting Agreement, dated February 20, 2024 (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Mr. Arthur is required to devote at least one-fourth (1/4) of his time on a weekly basis

(on average 10 or more hours/week) to performing the services set forth in the Consulting Agreement. In exchange for Mr. Arthur's services as set forth in the Consulting Agreement, Mr. Arthur will receive $10,417 per month. The term of the Consulting Agreement expires on February 20, 2025, unless earlier terminated by either party in accordance with the terms of the Consulting Agreement.

In addition, on the Separation Date, Salarius entered into a Notice of Stock Option Amendment with Mr. Arthur (the "Notice of Stock Option Amendment"), pursuant to which the Salarius board of directors amended the stock options to purchase shares of common stock granted to Mr. Arthur on September 10, 2019, March 23, 2020, July 14, 2020, December 2, 2020 and January 20, 2022 pursuant to Salarius' 2015 Equity Incentive Plan (the "Plan") to extend the post-termination exercise period from 90 days to 18 months upon the termination of Mr. Arthur's "Continuous Service" (as defined in the Plan) for any reason other than for "Cause" (as defined in the Plan), but not beyond the term of the applicable stock option, and subject to earlier termination (such as in connection with a "Corporate Transaction" (as defined in the Plan) as provided under the Plan.

Mr. Arthur also entered into an updated indemnification agreement with Salarius (the "Indemnification Agreement") to reflect his change in status from an employee of Salarius to a consultant.

Mark J. Rosenblum

On April 24, 2020, Salarius entered into an Executive Employment Agreement with Mark J. Rosenblum, its Executive Vice President of Finance and Chief Financial Officer (the "Rosenblum Agreement"). Under the Rosenblum Agreement, Mr. Rosenblum was originally entitled to an annual base salary of $265,000. Mr. Rosenblum is also eligible to participate in, subject to applicable eligibility requirements, all of Salarius' benefits plans and fringe benefits and programs that may be provided to Salarius executives from time to time. In December 2021 Mr. Rosenblum's base salary was increased to $300,000, which increase became effective January 1, 2022. In November 2022 Mr. Rosenblum's base salary was increased to $330,000, which increase became effective January 1, 2023. On February 20, 2024, Salarius entered into an amendment to the Rosenblum Agreement to provide Mr. Rosenblum with the option to receive any severance that may be owed to him pursuant to Section 5(c)(i) thereof in equal installments over a period of time or in a lump-sum amount.

Clawback Policy

Salarius has a compensation recoupment, or clawback, policy, which Salarius adopted to comply with Nasdaq listing standards implementing Exchange Act Rule 10D-1. The clawback policy includes mandatory recoupment of excess incentive-based compensation received by a covered executive (including the Named Executive Officers) on or after October 2, 2023 in the event of a restatement of Salarius' financial statements due to material non-compliance with any financial reporting requirement under federal securities laws, as required by Exchange Act Rule 10D-1.

Additional Narrative Disclosure: Termination-Based Compensation

The Rosenblum Agreement provides that, so long as Mr. Rosenblum executes a release and settlement agreement with Salarius, and subject to applicable withholdings, he would be entitled to receive a cash severance and an amount for premium payments under COBRA. Under the Rosenblum Agreement, the cash severance is equal to 9 months and if Mr. Rosenblum elects continuation coverage under COBRA or state law equivalent or enrollment in an individual marketplace, Salarius will pay him an amount equal to the 9 months' worth of total premium payments (or until the date the executive secures reasonably comparable coverage with another employer, if sooner). These payments to Mr. Rosenblum are required to be made upon the following termination events:

- In the event Salarius or a successor entity terminates the executive's employment for any reason other than a termination for Cause, or in connection with death, a permanent disability, or Salarius' dissolution; and
- In the event that, within the 18-month period following a Change in Control of Salarius or a successor entity terminates the executive's employment for any reason other than a termination for Cause or in connection with death, a permanent disability, or Salarius' dissolution, or if the executive terminates his employment for Good Reason.

The following definitions have been adopted in the Rosenblum Agreement:

"for Cause" shall be determined by the board of directors by a majority vote (not including such employee with respect to an event related to him) and shall mean:

- any material breach, which is not cured within 30 days after written notice thereof, of the terms of Rosenblum Agreement by the executive, or the failure of the executive to diligently and properly perform his duties, or the executive's failure to achieve the objectives specified by the board of managers;
- the executive's misappropriation or unauthorized use of the tangible or intangible property of Salarius, or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;
- any material failure to comply with Salarius company policies or any other policies and/or directives of the board of managers, which failure is not cured within 30 days after written notice thereof, provided that no cure period is available for a failure to comply with policies related to harassment, unlawful discrimination, retaliation or workplace violence;
- the executive's use of illegal drugs or any illegal substance, or alcohol in any manner that materially interferes with the performance of his duties under the Rosenblum Agreement;
- any dishonest or illegal action (including, without limitation, embezzlement) or any other action by the executive which is materially detrimental to the interest and well-being of Salarius, including, without limitation, harm to its reputation;
- the executive's failure to fully disclose to Salarius any material conflict of interest he may have in a transaction between Salarius and any third party which is materially detrimental to the interest and well-being of Salarius; or
- any adverse action or omission by the executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of Salarius or its affiliates to sell securities under any Federal or state law or which would disqualify Salarius or its affiliates from any exemption otherwise available to it.

"Good Reason" means the occurrence of any of the following actions taken by Salarius without the executive's consent, but only if (a) the executive informs Salarius within 90 days of its occurrence that an event constituting Good Reason has occurred, (b) Salarius fails to cure the event within 90 days of such notice, and (c) the executive terminates his employment within 6 months of the initial occurrence:

- for a period of twelve months immediately following a Change of Control, or the "Post-COC Period," his salary, bonus or equity are reduced or diminished, or his duties and responsibilities or position are reduced or diminished to less than an executive "C" level position;
- any time after the Post-COC Period, the executive's salary, bonus or equity are reduced or diminished, or his duties and responsibilities or position are reduced when compared to his duties and responsibilities immediately prior to Change of Control;
- Salarius materially breaches its obligations under the applicable Rosenblum Agreement; or
- the executive is required to relocate by more than 50 miles outside the extraterritorial jurisdiction of Houston, Texas.

"Change in Control" means (i) a financing transaction or any transaction designed to raise money for Salarius' continuing operations or any sale, exchange, transfer, or issuance, or related series of sales, exchanges, transfers, or issuances, of Salarius' equity units by Salarius or any holder thereof, in which the holders of Salarius' equity units immediately prior to such transaction or event no longer hold beneficial ownership of at least fifty percent (50%) of Salarius' outstanding equity units immediately after any such transaction or event; or (ii) a significant transaction

involving the out-licensing of Salarius' lead clinical asset, a sale of substantially all of Salarius' assets, or Salarius' liquidation or dissolution.

2024 Director Compensation

The following table sets forth the compensation to Salarius' non-employee directors that was paid or accrued by Salarius in 2024 pursuant to the non-employee director compensation policy described below.

Name[1]	Fees Earned or Paid in Cash[2]	Stock Options [3]	Total
Tess Burleson	$ 48,000	$ 9,944	$ 64,761
Arnold C. Hanish	$ 52,500	$ 9,944	$ 67,261
Paul Lammers	$ 51,750	$ 9,944	$ 76,761
Jonathan Lieber	$ 42,500	$ 9,944	$ 53,761
Bruce J. McCreedy	$ 37,000	$ 9,944	$ 45,261
William K. McVicar	$ 65,000	$ 9,944	$ 82,261

(1) Mr. Arthur is not included in this table as he is Salarius' chief executive officer and received no extra compensation for his service as a director while he was an employee of Salarius. The director fees received by Mr. Arthur following his cessation of employment is included in the Summary Compensation Table.
(2) The amounts listed in this column represent the retainer paid to each director for their service on the board and any committees on which they served during 2024.
(3) Salarius estimated the grant date fair value of the stock options in accordance with FASB ASC Topic 718.

Director Compensation Arrangements

Salarius' non-employee director compensation is comprised of cash compensation and equity compensation. Further, Salarius reimburses all of its non-employee directors for their reasonable expenses incurred in attending meetings of Salarius' board of directors and committees of the Salarius board of directors.

Generally, Salarius' board of directors believes that the level of director compensation should be based on time spent carrying out board of directors and committee responsibilities and be competitive with comparable companies. In addition, the Salarius board of directors believes that a significant portion of director compensation should align director interests with the long-term interests of stockholders. The Salarius board of directors makes changes in its director compensation practices only upon the recommendation of the Compensation Committee, and discussion and approval by the Salarius board of directors.

Salarius' board of directors, following the Compensation Committee's recommendation, has approved the compensation of Salarius' non-employee directors, as described below. The Compensation Committee believes that its non-employee director compensation remains aligned with director compensation practices at Salarius' peer companies while considering the ongoing cash constraints of Salarius.

Cash Compensation

On February 20, 2024, the Salarius board of directors approved a reduction in cash compensation payable to its non-employee directors. Effective as of April 1, 2024, non-employee directors receive an annual cash retainer of $30,000 (previously $40,000) for their board of directors service. In addition, the Chair of the board of directors receives an additional annual cash retainer of $20,000 (previously $40,000), the Chair of the Audit Committee of the board of directors receives an additional annual cash retainer of $10,000 (previously $20,000), and members of the Audit Committee will receive an additional annual cash retainer of $3,500 (previously $7,500). No additional cash retainers will be paid for serving as a Chair or member of the Compensation Committee of the board of directors or the Governance and Nominating Committee of the board of directors. Mr. Arthur is eligible to receive compensation as a non-employee member of the board of directors.

Outstanding Equity Awards for Directors

The following table provides information regarding the aggregate number of shares subject to outstanding stock options held by non-employee directors as of December 31, 2024:

Name	Number of Shares Subject to Outstanding Stock Options	Number of Restricted Shares of Common Stock
Tess Burleson	2,908	180
Arnold C. Hanish	2,908	180
Paul Lammers	2,908	180
Jonathan Lieber	2,878	180
Bruce J. McCreedy	2,908	180
William K. McVicar	2,908	180

Salarius Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

Salarius does not have any formal policy that requires Salarius to grant, or avoid granting, equity-based compensation to its executive officers at certain times. Consistent with its annual compensation cycle, the Compensation Committee has for several years granted annual equity awards to its executive officers in February of each year. The timing of any equity grants to executive officers in connection with new hires, promotions, or other non-routine grants is tied to the event giving rise to the award (such as an executive officer's commencement of employment or promotion effective date). As a result, in all cases, the timing of grants of equity awards, including stock options, occurs independent of the release of any material nonpublic information, and Salarius does not time the disclosure of material nonpublic information for the purpose of affecting the value of equity-based compensation.

The following table presents information regarding stock options issued to certain of Salarius' executive officers in 2024 during any period beginning four business days before the filing of a periodic report or current report disclosing material non-public information and ending one business day after the filing or furnishing of such report with the SEC.

Name	Grant Date	Number of Securities Underlying the Award	Exercise Price of the Award	Grant Date Fair Value of the Award	Percentage Change in the Closing Market Price of the Securities Underlying the Award Between the Trading Day Ending Immediately Prior to the Disclosure of Material Nonpublic Information and the Trading Day Beginning Immediately Following the Disclosure of Material Nonpublic Information
Mark J. Rosenblum	02/20/2024	2,813	$ 4.5688	$ 11,372	3.2 %

DECOY EXECUTIVE COMPENSATION

The following information is related to the compensation earned in fiscal 2024 and 2023 by all Chief Executive Officers (principal executive officers) serving Decoy during the last fiscal year and the other most highly compensated executive officers serving at the end of the last fiscal year whose compensation exceeded $100,000.

Decoy Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Frederick Pierce II	2024	175,000	—	—	—	—	175,000
Chief Executive Officer	2023	175,000	—	—	—	—	175,000
Peter Marschel	2024	175,000	—	—	—	—	175,000
Chief Business Officer	2023	175,000	—	—	—	—	175,000
Barbara Hibner	2024	175,000	—	—	—	—	175,000
Chief Scientific Officer	2023	175,000	—	—	—	—	175,000

Narrative to Decoy Summary Compensation Table

Decoy's executive officers are each paid an annual base salary of $175,000 under oral employment arrangements. Decoy anticipates entering into written employment agreements with its executive officers prior to or shortly after the Merger Closing on terms commensurate with market for executives with their skills and positions. As part of these new agreements, Decoy anticipates each of its executive officers receiving a grant of stock options. As of December 31, 2024, each executive officer had stock options outstanding exercisable for 30,000 shares of Decoy common stock, at an exercise price of $0.833 per share. Such options will be assumed in the Merger and exchanged (in an amount based on the exchange ratio) for stock options to purchase Salarius shares.

Decoy Therapeutics, Inc. 2020 Equity Incentive Plan

On May 25, 2020 the Board of Directors of Decoy adopted and its stockholders approved The Decoy Therapeutics, Inc. Equity Incentive Plan ("Decoy's 2020 Plan"). In connection with the Merger, Salarius will assume Decoy's 2020 Plan. As January 10, 2025, there were outstanding options to purchase a total of 966,000 Decoy's Common Shares issued and outstanding under Decoy's 2020 Plan and 3,930 restricted Decoy Common Shares had been granted under Decoy's 2020 Plan. Upon the Merger Closing, we anticipate that no additional awards will be granted under the Decoy's 2020 Plan, and all awards will be granted under a new equity plan to be approved by the combined company's Board and its stockholders. Capitalized terms used but not defined herein shall have the respective meanings given to them in Decoy's 2020 Plan.

Description of Decoy's 2020 Plan

Decoy's 2020 Plan is designed to attract, retain, and motivate key employees, officers, directors, and consultants by aligning their interests with those of the company's stockholders. Decoy's 2020 Plan, dated May 25, 2020, authorizes the grant of various equity awards of non-qualified stock options, incentive stock options (ISOs under Section 422 of the Internal Revenue Code) and Restricted Awards (including Restricted Shares and Restricted Share Units).

Decoy's 2020 Plan is administered by the Board, which has the authority to interpret and apply Decoy's 2020 Plan's provisions, select participants, determine award terms and conditions, and make other necessary administrative decisions. The Board may also delegate day-to-day administration to company officers or employees. The Awards generally cannot be transferred, assigned, or sold, with exceptions allowed for a transfer by will or laws of descent, Board-approved transfers and ISOs may only be exercised by the participant or their estate.

Stock Options

Decoy's 2020 Plan allows for the grant of both non-qualified stock options and ISOs. Options grant the right to purchase Common Shares at a specified exercise price. The exercise price for non-qualified stock options must be no less than 100% of the Fair Market Value of the Common Shares on the date of grant (or no less than 110% of the Fair Market Value for 10% stockholders with ISOs). ISOs are subject to additional requirements under the Internal Revenue Code. The term of options is generally ten (10) years from the vesting commencement date (or five (5) years for 10% stockholders with ISOs). Vesting schedules are determined by the Board but typically involve a combination of time-based vesting and cliff vesting, with 25% vests after the first year and remaining 75% vests monthly over the next 3 years (1/48 per month). Options may be exercised by delivering an Exercise Notice and payment of the exercise price. Payment can be made in cash or, if approved by the Board, through net settlement.

Restricted Awards

Restricted Awards, which can be Restricted Shares or Restricted Share Units, are subject to a Restricted Period determined by the Board, generally commencing on the Date of Grant and ending no earlier than four (4) years later.

The Restricted Period may be shortened if the Awardee is terminated, resigns, dies, or becomes disabled before the fourth anniversary of the Date of Grant. Restricted Shares grant the Awardee the rights of a stockholder, including voting and dividend rights, subject to restrictions outlined in the Award Agreement. Restricted Share Units do not grant voting rights and are settled by delivering Common Shares or cash equivalent to their Fair Market Value upon expiration of the Restricted Period.

Changes in Capital Structure and Change in Control

Decoy's 2020 Plan addresses changes in the company's capital structure, such as stock splits, mergers, consolidations, other reorganization or share dividends. In such cases, the Board may take various actions regarding outstanding Awards. These actions may include converting options into shares or securities of the surviving entity, accelerating vesting, purchasing outstanding Options at a favorable price or cancel outstanding unvested Options if their exercise price exceeds the Change in Control price. In the event of Decoy's reorganization of capital structure, the Board may also adjust the number of shares subject to outstanding Awards and the exercise price of Options to maintain the proportionate rights and obligations of the awardees.

In the event of a merger, acquisition, or other reorganization, the Board may take various actions regarding outstanding awards. These actions may include converting options into shares or securities of the surviving entity, accelerating vesting, purchasing outstanding Options or cancel outstanding unvested Options. Under Decoy's 2020 Plan, a Change in Control is generally an acquisition of 50% of the outstanding voting power or through significant mergers, consolidations, or asset sales. Exceptions include transactions with related entities, changes in domicile, equity financing, or an IPO, unless the Board decides otherwise.

PRINCIPAL STOCKHOLDERS OF SALARIUS

The following table sets forth information as of January 14, 2025 regarding the number of shares of common stock and the percentage of common stock, beneficially owned by:

- each person, or group of affiliated persons, known by Salarius to beneficially own more than 5% of its common stock;
- each of Salarius' directors;
- each of Salarius' named executive officers; and
- all of Salarius' current executive officers and directors as a group.

The percentage ownership is based on 1,583,576 shares of common stock outstanding on January 14, 2025. Salarius has determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of Salarius' common stock issuable pursuant to the exercise of stock options or warrants or other securities (including out-of-the-money securities) that are either immediately exercisable or exercisable or vest within 60 days of January 14, 2025. These shares are deemed to be outstanding and beneficially owned by the person holding those options, warrants, or securities for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Salarius Pharmaceuticals, Inc., 2450 Holcombe Blvd., Suite X, Houston, TX 77021.

	Shares of Common Stock Beneficially Owned	Percent of Common Stock Outstanding
Beneficial Owner		
David J. Arthur[(1)]	11,601	*
Mark J. Rosenblum[(2)]	5,098	*
Tess Burleson[(3)]	3,269	*
Arnold C. Hanish[(4)]	3,341	*
Jonathan Lieber[(5)]	3,246	*
Paul Lammers[(6)]	3,123	*
Bruce J. McCreedy[(7)]	3,131	*
William K McVicar[(8)]	3,308	*
All current executive officers and directors as a group (8 persons) [(9)]	36,117	1.50 %

* Represents beneficial ownership of less than 1%.

(1) Represents (i) 6,142 shares of common stock, (ii) 5,449 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025 and (iii) 10 warrants to purchase shares of common stock.

(2) Represents (i) 2,731 shares of common stock and (ii) 2,367 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025.

(3) Includes (i) 340 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025, and (iii) 21 warrants to purchase shares of common stock.

(4) Includes (i) 412 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025, and (iii) 21 warrants to purchase shares common stock.

(5) Includes (i) 368 shares of common stock, (ii) 2,878 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025.

(6) Includes (i) 215 shares of common stock and (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025.

(7) Includes (i) 180 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days of January 14, and (iii) 43 warrants to purchase shares of common stock.
(8) Includes (i) 357 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days of January 14, and (iii) 43 warrants to purchase shares of common stock.
(9) Includes (i) 10,745 shares of common stock, (ii) 25,234 shares of common stock subject to options that are exercisable within 60 days of January 14, 2025, and (iii) 138 warrants to purchase shares of common stock that are held by Salarius' executive officers and directors as a group.

PRINCIPAL STOCKHOLDERS OF THE COMBINED COMPANY

The following table provides information anticipated as of the Merger Closing, regarding beneficial ownership of 5% or more of Salarius' common stock by: (i) each person known to Salarius who beneficially owns more than five percent of Salarius' common stock; (ii) each of the expected officers and directors of the combined company. The following table assumes (i) no adjustment to the exchange ratio based on Salarius or Decoy cash at Merger Closing, (ii) 3,333,333 shares of Salarius Common Stock will be issued in the Qualified Financing (based on the closing price of Salarius Common Stock on January 6, 2025) and (ii) conversion of the Salarius preferred stock to be issued at Merger Closing into common stock at a ratio of 1:1,000.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days after the Merger Closing. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. The shares in the tables does not, however, constitute an admission that the named stockholder is a direct or indirect beneficial owner of those shares.

Name and Address	Beneficial Ownership	Percent of Class[1]
Stockholders of 5% or more[2]	—	—
Officers and Directors		
Frederick E. Pierce[3]	760,495	6.4 %
Barbara Hibner[4]	760,495	6.4 %
Peter Marschel[5]	760,495	6.4 %
Mark J. Rosenblum[6]	5,098	*
Tess Burleson[7]	3,269	*
Arnold C. Hanish[8]	3,341	*
Jonathan Lieber[9]	3,246	*
Paul Lammers[10]	3,123	*
Bruce J. McCreedy[11]	3,131	*
William K McVicar[12]	3,308	*
David J. Arthur[13]	11,601	*
All Directors and Officers as a group[14]	2,317,602	19.4 %

* Represents beneficial ownership of less than 1%.

(1) Applicable percentage ownership is based on 11,870,060 shares of common stock outstanding including and assuming the full conversion of Decoy's holders of convertible notes and assumed issuance of shares in the Qualified Financing. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock that are currently exercisable or exercisable within 60 days of January 10, 2025 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage of ownership of such person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

(2) Other than executive officers of the post-Merger management team, Salarius does not expect any individual stockholder to beneficially own more than 5.0% or more of the common stock of the combined company on a pro forma basis, as the Certificate of Designations for the Preferred Stock provides for a cap on conversion to the extent such conversion would result in beneficial ownership of over 4.99% of Salarius' Common Stock.

(3) Represents (i) 685,590 shares of common stock and (ii) 74,905 shares of common stock subject to options that are exercisable within 60 days.

(4) Represents (i) 685,590 shares of common stock and (ii) 74,905 shares of common stock subject to options that are exercisable within 60 days.

(5) Represents (i) 685,590 shares of common stock and (ii) 74,905 shares of common stock subject to options that are exercisable within 60 days.

(6) Represents (i) 2,731 shares of common stock and (ii) 2,367 shares of common stock subject to options that are exercisable within 60 days.

(7) Represents (i) 340 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days, and (iii) 21 warrants to purchase shares of common stock.
(8) Represents (i) 412 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days, and (iii) 21 warrants to purchase shares of common stock.
(9) Represents (i) 368 shares of common stock and (ii) 2,878 shares of common stock subject to options that are exercisable within 60 days.
(10) Represents (i) 215 shares of common stock and (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days.
(11) Represents (i) 180 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days, and (iii) 43 warrants to purchase shares of common stock.
(12) Represents (i) 357 shares of common stock, (ii) 2,908 shares of common stock subject to options that are exercisable within 60 days, and (iii) 43 warrants to purchase shares of common stock.
(13) Represents (i) 6,142 shares of common stock, (ii) 5,449 shares of common stock subject to options that are exercisable within 60 days, and (iii) 10 warrants to purchase shares of common stock.
(14) Represents (i) 2,067,515 shares of common stock, (ii) 249,949 shares of common stock subject to options that are exercisable within 60 days, and (iii) 138 warrants to purchase shares of common stock.

CERTAIN RELATIONSHIP AND RELATED PARTY TRANSACTIONS OF SALARIUS

The following includes a summary of transactions since January 1, 2023 to which Salarius been a party, in which the amount involved in the transaction exceeded the lesser of $120,000 or one percent of the average of Salarius' total assets at year-end for the last two completed fiscal years, and in which any of Salarius' directors, executive officers or, to Salarius' knowledge, beneficial owners of more than 5% of Salarius' capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change of control, and other arrangements, which are described under "*Salarius Executive Compensation*."

DeuteRx Transaction

On January 12, 2022, Salarius entered into an Acquisition and Strategic Collaboration Agreement (the "ASCA"), with DeuteRx, LLC, a Delaware limited liability company (the "DeuteRx"), pursuant to which DeuteRx agreed to sell, and Salarius agreed to purchase certain assets of DeuteRx, including the development product Salarius refers to as DRX-3164 (collectively, the "Purchased Assets"). Dr. McVicar, a member of the Salarius board of directors, serves as a consultant to DeuteRx and is a consultant to an affiliate of DeuteRx.

The Purchased Assets were purchased for an aggregate purchase price of $1,500,000 and the delivery of 5,000 shares of Salarius' common stock. Salarius also agreed to pay to DeuteRx (i) milestone payments upon the occurrence of certain events and (ii) royalty payments.

Indemnification Agreements

Salarius has entered, and intends to continue to enter, into separate indemnification agreements with its directors and executive officers, in addition to the indemnification provided for in its Certificate of Incorporation and Bylaws. These agreements, among other things, require Salarius to indemnify its directors and executive officers for certain expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of Salarius' directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at Salarius' request. Salarius believes that these charter provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in Salarius' Certificate of Incorporation and Bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit Salarius and its stockholders. A stockholder's investment may decline in value to the extent Salarius pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Policies and Procedures for Transactions with Related Persons

Salarius has adopted a written Related Person Transactions Policy that sets forth its policies and procedures regarding the identification, review, consideration, and oversight of "related person transactions." For purposes of this policy only, a "related person transaction" is a transaction, arrangement, or relationship (or any series of similar transactions, arrangements or relationships) in which Salarius or any of its subsidiaries are participants involving an amount that exceeds $120,000, in which any "related person" has a material interest.

Transactions involving compensation for services provided to Salarius as an employee, consultant, or director are not considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of Salarius' voting securities (including its common stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of Salarius' voting securities, an officer with knowledge of the proposed transaction, must present

information regarding the proposed related person transaction to Salarius' Audit Committee (or, where review by the Audit Committee would be inappropriate, to another independent body of the Salarius board of directors) for review. To identify related person transactions in advance, Salarius relies on information supplied by its executive officers, directors, and certain significant stockholders. In considering related person transactions, Salarius' Audit Committee considers the relevant available facts and circumstances, which may include, but not limited to:

- the risks, costs, and benefits to Salarius;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

Salarius' Audit Committee will approve only those transactions that it determines are fair to Salarius and in its best interests.

CERTAIN RELATIONHIPS AND RELATED PARTY TRANSACTIONS OF DECOY

Related Party Transactions

As of December 31, 2024, Mr. Frederick (Rick) Pierce, an executive officer and founder of Decoy, had an outstanding Demand Note in the principal amount of $55,555, plus accrued interest of $9,002, which Decoy issued in June 2023 (the "Demand Note"). This Demand Note accrues interest at 10% and has a maturity date of December 28, 2024. The Demand Note is recorded as debt on the balance sheet, and interest expense is recognized accordingly.

During the second half of 2024, each of Rick Pierce, Barbara Hibner, Decoy's Chief Scientific Officer, and Peter Marschel, Decoy's Chief Business Officer, issued non-interest bearing notes in the amount of $51,873, $48,000, and $24,000, respectively.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes certain important terms of Salarius' capital stock as of the date of this prospectus as specified in Salarius' Charter and Bylaws. Because the following description is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this section entitled "Description of Securities," you should refer to the Charter, the Bylaws, and the Certificate of Designations of Preferences, Rights and Limitations of the Series A Convertible Preferred Stock (the "Certificate of Designations") which are included as exhibits to the registration statement of which this prospectus is a part, and to the applicable provisions of Delaware law.

The following description does not summarize the terms of the warrants offered in this offering. For a description summarizing the important terms of the warrants, please refer to the section entitled "Description of Securities Salarius is Offering" herein.

Authorized Capital Stock

Salarius is authorized to issue up to 110,000,000 shares, of which (i) 100,000,000 have been designated common stock, par value $0.0001 per share, and (ii) 10,000,000 have been designated preferred stock, par value $0.0001 per share. As of January 14, 2025, there were 1,583,567 shares of Salarius' common stock outstanding, held by 139 stockholders of record. This figure does not reflect the number of beneficial owners of shares of Salarius' common stock as a single stockholder of record often holds shares in nominee name (also referred to as, in "street name") on behalf of multiple beneficial owners.

Voting Rights

The holders of shares of Salarius' common stock have the exclusive power to vote on all matters presented to them unless Delaware law or the certificate of designation for an outstanding series of Salarius' preferred stock gives the holders of that series of preferred stock the right to vote on certain matters. Each holder of shares of Salarius' common stock is entitled to one vote per share.

When a quorum is present at any meeting, the vote of the holders of a majority of the voting power of Salarius' common stock entitled to vote and present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which by express provision of the Charter Documents or by law, a different vote is required in which case such express provision shall govern and control the decision of such question. Directors are elected by a plurality of the voting power of the shares present in person or represented by proxy and entitled to vote on the election of directors at a meeting at which a quorum is present, and stockholders are not entitled to cumulate their votes for the election of directors.

Dividend Rights

Subject to any prior rights of any preferred stock then outstanding, the holders of shares of Salarius' common stock are entitled to receive dividends ratably out of funds legally available, when and if declared by Salarius' board of directors.

No Preemptive or Similar Rights

Salarius' common stock is not entitled to preemptive rights and is not subject to conversion, redemption or sinking fund provisions.

Rights to Receive Liquidation Distributions

If Salarius becomes subject to a liquidation, dissolution or winding-up, the assets legally available for distribution to its stockholders would be distributable ratably among the holders of its common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights and payment of liquidation preferences, if any, on any outstanding shares of its preferred stock.

Description of Series A Preferred Stock

Preferred Stock

Salarius' board of directors is authorized, subject to limitations prescribed by Delaware law, to issue Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of their qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Subject to the Certificate of Designation, our board of directors can also increase or decrease the number of shares of any series of Preferred Stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our Common Stock. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and might adversely affect the market price of our Common Stock and the voting and other rights of the holders of our Common Stock. We have no current plan to issue any shares of Preferred Stock other than the shares of our Series A Preferred Stock to be issued to Decoy stockholders in connection with the Merger.

Series A Preferred Stock

Upon the filing of the Certificate of Designations, holders of Series A Preferred Stock will be entitled to receive dividends on shares of Series A Preferred Stock equal to, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of our Common Stock. Except as provided in the Series A Certificate of Designation or as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock: (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, or alter or amend the Series A Certificate of Designation, amend or repeal any provision of, or add any provision to, our Certificate of Incorporation or its Bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series A Preferred Stock, regardless of whether any of the foregoing actions will be by means of amendment to the Certificate of Incorporation or by merger, consolidation, recapitalization, reclassification, conversion or otherwise, (b) issue further shares of Series A Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock, (c) authorize, create or issue classes or series of equity securities other than Junior Securities; (d) authorize, create and/or issue any funded indebtedness (other than indebtedness already incurred); (e) sell or transfer, other than in the ordinary course of its business, mortgage, assign, pledge, lease, grant a security interest in, or encumber any of the Corporation's assets or (f) enter into any agreement with respect to any of the foregoing. The Series A Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of Salarius.

Following stockholder approval of the Series A Conversion Proposal, each share of Series A Preferred Stock will be automatically converted into 1,000 shares of Common Stock, subject to certain limitations, including that no holder, together with its affiliates, may convert shares of Series A Preferred Stock in excess of 4.99% of the then issued and outstanding Common Stock after giving effect to the issuance of shares in connection with the conversion (the "Beneficial Ownership Limitation"), subject to the each holder's right, upon 61 days prior written notice to Salarius, to increase the Beneficial Ownership Limitation to 9.99%.

Provisions of Salarius' Certificate of Incorporation and Bylaws and Delaware Anti-Takeover Law

Certain provisions of the Charter Documents, which are summarized below, may have the effect of delaying, deferring or preventing another person from acquiring control of Salarius. These provisions may discourage takeovers, coercive or otherwise, and are also designed, in part, to encourage persons seeking to acquire control of Salarius to negotiate first with its board of directors. Salarius believes that the benefits of increased protection of Salarius' potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of

discouraging a proposal to acquire Salarius because negotiation of these proposals could result in an improvement of their terms. These provisions include the following:

Board of Directors Vacancies. Pursuant to the Charter Documents, the board of directors may fill vacant directorships. In addition, directors may only be removed for cause and only upon the affirmative vote of at least sixty-six and two-thirds percent of the voting power of outstanding voting stock. In addition, the number of directors constituting the board of directors may be set only by a resolution adopted by a majority vote of the board of directors. These provisions may have the effect of deferring, delaying or discouraging hostile takeovers, or changes in control or management of Salarius and will make it more difficult to change the composition of the board of directors, which will promote continuity of management.

Classified Board. The Charter Documents provide that the board of directors is classified into three classes of directors, with each class serving three-year staggered terms. A third-party may be discouraged from making a tender offer or otherwise attempting to obtain control of Salarius as it is more difficult and time-consuming for stockholders to replace a majority of the directors on a classified board of directors.

Stockholder Action; Special Meeting of Stockholders. Pursuant to Section 228 of the Delaware General Corporation Law (the "DGCL"), any action required to be taken at any annual or special meeting of the stockholders may be taken without a meeting, without prior notice and without a vote if a consent or consents in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of stock entitled to vote thereon were present and voted, unless the Certificate of Incorporation provides otherwise. The Certificate of Incorporation provides that stockholders may not take action by written consent but may only take action at annual or special meetings of stockholders. As a result, a holder controlling a majority of Salarius' capital stock would not be able to amend the Bylaws or remove directors without holding a meeting of stockholders called in accordance with the Charter Documents. The Bylaws provide that special meetings of the stockholders may be called only upon a resolution approved by a majority of the total number of directors that the board of directors would have if there were no vacancies. These provisions might delay the ability of Salarius' stockholders to force consideration of a proposal or for stockholders controlling a majority of Salarius' capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. The Bylaws provide advance notice procedures for stockholders seeking to bring business before Salarius' annual meeting of stockholders (the "Annual Meeting") or to nominate candidates for election as directors at the Annual Meeting. The Bylaws specify certain requirements regarding the form and content of a stockholder's notice and prohibit the conduct of any business at a special meeting other than as specified in the notice for such meeting. These provisions might preclude stockholders from bringing matters before the Annual Meeting or from making nominations for directors at the Annual Meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of Salarius.

No Cumulative Voting. The DGCL provides that stockholders are not entitled to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. The Certificate of Incorporation does not provide for cumulative voting.

Amendment of Charter Provisions and Bylaws. The Charter Documents provides that the Bylaws may be adopted, amended, altered or repealed by either (i) a vote of a majority of the total number of directors of the board of directors or (ii) in addition to any other vote otherwise required by law, the affirmative vote of the holders of at least sixty-six and two-thirds percent of the voting power of all of the then outstanding shares of capital stock entitled to vote generally in the election of directors.

The Charter Documents also provide that the provisions of the Certificate of Incorporation relating to provisions relating to the management of the business, board of directors, director liability, indemnification and forum selection, may only be amended, altered, changed or repealed by the affirmative vote of the holders of at least sixty-

six and two-thirds percent of the voting power of all of Salarius' outstanding shares of capital stock entitled to vote generally in the election of directors, voting together as a single class.

Issuance of Undesignated Preferred Stock. The board of directors has the authority, without further action by Salarius' stockholders, to designate and issue shares of preferred stock with rights and preferences, including super voting, special approval, dividend or other rights or preferences on a discriminatory basis. The existence of authorized but unissued shares of undesignated preferred stock would enable the board of directors to render more difficult or to discourage an attempt to obtain control of Salarius by means of a merger, tender offer, proxy contest or other means.

Business Combinations with Interested Stockholders. Salarius is subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination, such as a merger, with an interested stockholder (i.e., subject to certain exceptions, a person or group owning 15% or more of the corporation's voting stock) for a period of three years following the date the person became an interested stockholder, unless (with certain exceptions) the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner.

Forum Selection. The Charter Documents provide that unless Salarius consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for:

- any derivative action or proceeding brought on behalf of Salarius;
- any action asserting a claim of breach of a fiduciary duty owed by any of Salarius' directors, officers, or other employees to Salarius or its stockholders;
- any action asserting a claim of breach of a fiduciary duty owed by any of Salarius' directors, officers, or other employees to Salarius or its stockholders; and
- any action asserting a claim against Salarius governed by the internal affairs doctrine,

in each such case, subject to such Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein. The Charter Documents also provides that any person or entity purchasing or otherwise acquiring any interest in shares of Salarius' capital stock will be deemed to have notice of, and to have consented to, this forum selection provision.

Although these provisions benefit Salarius by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of increasing the costs of and discouraging lawsuits against Salarius' directors, officers, employees and agents. The enforceability of similar exclusive forum provisions in other companies' charters has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could rule that this provision in the Certificate of Incorporation is inapplicable or unenforceable. For example, the choice of forum provisions summarized above are not intended to, and would not, apply to suits brought to enforce any liability or duty created by the Exchange Act, or other claim for which the federal courts have exclusive jurisdiction. Additionally, there is uncertainty as to whether Salarius' choice of forum provisions would be enforceable with respect to suits brought to enforce any liability or duty created by the Securities Act, or other claims for which the federal courts have concurrent jurisdiction, and in any event stockholders will not be deemed to have waived Salarius' compliance with federal securities laws and rules and regulations thereunder.

Listing

Salarius' common stock is listed on The Nasdaq Capital Market under the symbol "SLRX."

Transfer Agent and Registrar

The transfer agent and registrar for Salarius' common stock is Equiniti Trust Company, LLC.

DESCRIPTION OF SECURITIES SALARIUS IS OFFERING

The following summary of certain terms and provisions of the securities that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the underlying securities, the forms of which will be filed as exhibits to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of securities for a complete description of the terms and conditions.

Common Stock

The material terms and provisions of Salarius' common stock and each other class of its securities which qualifies or limits its common stock are described under the caption "*Description of Capital Stock*" in this prospectus.

Description of Pre-Funded Warrants

The following summary of certain terms and provisions of pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. You should review the form of pre-funded warrant for a complete description of the terms and conditions applicable to the pre-funded warrants.

Form. Pursuant to a warrant agency agreement between Salarius and Equiniti Trust Company, LLC, as warrant agent, the pre-funded warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company ("DTC"), and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to Salarius a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of Salarius' common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of Salarius' outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to Salarius, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of Salarius' common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of Salarius' outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, Salarius will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share.

Duration and Exercise Price. The exercise price per whole share of Salarius' common stock purchasable upon the exercise of the pre-funded warrants is $0.0001 per share of common stock. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting Salarius' common stock and upon any distributions of assets, including cash, stock or other property to Salarius' stockholders.

Cashless Exercise. If, at any time after the holder's purchase of pre-funded warrants, such holder exercises its pre-funded warrants, then in lieu of making the cash payment otherwise contemplated to be made to Salarius upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability. Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the pre-funded warrant to Salarius together with the appropriate instruments of transfer.

Exchange Listing. Salarius does not plan on applying to list the pre-funded warrants on Nasdaq, any other national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be limited.

Fundamental Transactions. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of Salarius' common stock, the sale, transfer or other disposition of all or substantially all of Salarius' properties or assets, consolidation or merger with or into another person, the acquisition of more than 50% of Salarius' outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by Salarius' outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of Salarius' common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of Salarius' common stock, including any voting rights, until the holder exercises the pre-funded warrant.

Description of Representative Warrants

The following summary of certain terms and provisions of representative warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the representative warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. You should review the form of representative warrant for a complete description of the terms and conditions applicable to the representative warrants.

Form. The representative warrants will be issued in certificated forms only.

Exercisability. The representative warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to Salarius a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of Salarius' common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of Salarius' outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to Salarius, the holder may increase the amount of ownership of outstanding stock after exercising the holder's representative warrants up to 9.99% of the number of shares of Salarius' common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the representative warrants. Holders of representative warrants in this offering may also elect prior to the issuance of the representative warrants to have the initial exercise limitation set at 9.99% of Salarius' outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a representative warrant. In lieu of fractional shares, Salarius will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share.

Duration and Exercise Price. The exercise price per whole share of Salarius' common stock purchasable upon the exercise of the representative warrants is $ per share of common stock. The representative warrants will be immediately exercisable upon issuance and may be exercised at any time until the five year anniversary of the commencement of sales of the offering. The exercise price of the representative warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting Salarius' common stock and upon any distributions of assets, including stock or other property to Salarius' stockholders.

Cashless Exercise. If, at any time after the holder's receipt of representative warrants, such holder exercises its representative warrants and a registration statement registering the issuance of the shares of common stock

underlying the representative warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the representative warrants), then in lieu of making the cash payment otherwise contemplated to be made to Salarius upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the representative warrants.

Transferability. Subject to applicable laws, the representative warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the pre-funded warrant to Salarius together with the appropriate instruments of transfer.

Exchange Listing. Salarius does not plan on applying to list the representative warrants on Nasdaq, any other national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the representative warrants will be limited.

Fundamental Transactions. In the event of a fundamental transaction, as described in the representative warrants and generally including any reorganization, recapitalization or reclassification of Salarius' common stock, the sale, transfer or other disposition of all or substantially all of Salarius' properties or assets, consolidation or merger with or into another person, the acquisition of more than 50% of Salarius' outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by Salarius' outstanding common stock, the holders of the representative warrants will be entitled to receive upon exercise of the representative warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the representative warrants immediately prior to such fundamental transaction. Additionally, as more fully described in the representative warrants, in the event of certain fundamental transactions, the holders of the representative warrants will be entitled to receive consideration in an amount equal to the Black-Scholes value of the representative warrants on the date of consummation of the transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of Salarius' common stock, the holder of a representative warrant does not have the rights or privileges of a holder of Salarius' common stock, including any voting rights, until the holder exercises the representative warrant.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following discussion is a summary of the material U.S. federal income tax consequences of the purchase, ownership and disposition of shares of Salarius' common stock and pre-funded warrants issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax consequences, including estate and gift tax laws, and any applicable state, local or non-U.S. tax laws. This discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a holder of Salarius' common stock or pre-funded warrants. Salarius has not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of Salarius' common stock or pre-funded warrants.

This discussion is limited to holders that hold Salarius' common stock or pre-funded warrants as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances, including the impact of the alternative minimum tax or the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to holders subject to special rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the U.S.;
- persons holding Salarius' common stock or pre-funded warrants as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- controlled foreign corporations, "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell Salarius' common stock or pre-funded warrants under the constructive sale provisions of the Code;
- persons for whom Salarius' common stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- persons who hold or receive Salarius' common stock or pre-funded warrants pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(1)(2) of the Code and entities, all of the interests of which are held by qualified foreign pension funds.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds Salarius' common stock or pre-funded warrants, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding Salarius' common stock or pre-funded warrants and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF SALARIUS' COMMON STOCK OR PRE-FUNDED WARRANTS ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

For purposes of this discussion, a "U.S. holder" is any beneficial owner of Salarius' common stock or pre-funded warrants that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the U.S.;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the U.S., any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to continue to be treated as a U.S. person.

For purposes of this discussion, a "non-U.S. holder" is a beneficial owner of Salarius' common stock or pre-funded warrants that is neither a U.S. holder nor an entity treated as a partnership for U.S. federal income tax purposes.

General Treatment of Pre-Funded Warrants

Although the law in this area is not completely settled, the pre-funded warrants are generally expected to be treated as shares of Salarius' common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. You should discuss with your tax advisor the consequences of the purchase, ownership and disposition of the pre-funded warrants, as well as the exercise of, certain adjustments to, and any payments in respect of the pre-funded warrants (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Distributions

Salarius does not anticipate declaring or paying distributions to holders of its common stock in the foreseeable future. However, if Salarius does make distributions on its common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from Salarius' current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both Salarius' current and accumulated earnings and profits, the excess will constitute a return of capital and will first reduce a U.S. holder's basis in Salarius' common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "—Gain on Disposition of Salarius' Common Stock or pre-funded warrants." A preferential U.S. federal income tax rate may apply to any dividends paid to noncorporate U.S. holders meeting certain holding period requirements.

Gain on Disposition of Salarius' Common Stock or Pre-Funded Warrants

Upon a sale or other taxable disposition of Salarius' common stock or pre-funded warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the common stock or pre-funded warrant. Capital gain or loss will constitute long-term capital gain or loss if such U.S. holder's holding period for the common stock or pre-funded warrant exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. holders who recognize

losses with respect to a disposition of Salarius' common stock or pre-funded warrants should consult their own tax advisors regarding the tax treatment of such losses.

Exercise of Pre-Funded Warrants

As discussed above under the section titled "Description of Pre-Funded Warrants—Exercisability," a U.S. holder may exercise the pre-funded warrant by payment of exercise price or through a cashless exercise. The U.S. federal income tax treatment of a cashless exercise of pre-funded warrants into Salarius' common stock is unclear, and a U.S. holder should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of pre-funded warrants. In general, however, a U.S. holder should not recognize gain or loss for U.S. federal income tax purposes upon exercise of a pre-funded warrant pursuant to either method, except to the extent such U.S. holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the pre-funded warrant, which will be treated as a sale subject to the rules described above under "—Gain on Disposition of Salarius' Common Stock or Pre-Funded Warrants." A U.S. holder's initial tax basis in the share of common stock received upon exercise of the pre-funded warrant generally should be equal to the sum of (i) such U.S. holder's tax basis in the pre-funded warrant and (ii) the exercise price paid or treated as paid by such U.S. holder on the exercise of the pre-funded warrant. A U.S. holder's holding period in the common stock received upon exercise generally should include such U.S. holder's holding period in the pre-funded warrants exchanged therefor.

The taxation of property received with respect to a pre-funded warrant on exercise other than common shares is unclear. It is possible such a receipt of property would be treated as a distribution on common stock as described above, although other treatments may also be possible. Prospective investors should consult their tax advisors regarding the proper treatment of any such receipt of property in respect of the pre-funded warrants on exercise.

Certain Adjustments to the Pre-Funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the pre-funded warrants, or an adjustment to the exercise price of the pre-funded warrants, may be treated as a constructive distribution to a U.S. holder of the pre-funded warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. holder's proportionate interest in Salarius' earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to Salarius' shareholders).

Lapse of Pre-Funded Warrants

If a U.S. holder allows a pre-funded warrant to expire unexercised, such U.S. holder will recognize a capital loss in an amount equal to such U.S. holder's tax basis in pre-funded warrant. The deductibility of capital losses is subject to certain limitations.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock and to the proceeds of a sale or other disposition of common stock or pre-funded warrants paid by Salarius to a U.S. holder unless such U.S. holder is an exempt recipient, such as certain corporations. Backup withholding will apply to those payments if a U.S. holder fails to provide their taxpayer identification number, or certification of exempt status, or if a U.S. holder otherwise fails to comply with applicable requirements to establish an exemption.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability, if any, provided the required information is timely furnished to the IRS. Prospective investors should consult their own tax advisors regarding their qualification for exemption from information reporting and backup withholding and the procedure for obtaining such exemption.

Tax Consequences Applicable to Non-U.S. Holders

Distributions

Salarius does not anticipate declaring or paying distributions to holders of its common stock in the foreseeable future. However, if Salarius does make distributions on its common stock, such distributions of cash or property will constitute dividends for U.S. federal income tax purposes to the extent paid from Salarius' current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below in the section relating to the sale or disposition of Salarius' common stock. Because Salarius may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below Salarius or the applicable withholding agent may treat the entire distribution as a dividend.

Subject to the discussion below on backup withholding and FATCA, dividends paid to a non-U.S. holder that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the U.S. will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders may be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the non-U.S. holder holding Salarius' common stock in connection with the conduct of a trade or business within the U.S. and dividends being effectively connected with that trade or business. To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the U.S. and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the U.S., as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the U.S. (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the U.S. to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular graduated U.S. federal income tax rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Sale or Other Disposition of Common Stock or Pre-Funded Warrants

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of Salarius' common stock or pre-funded warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the U.S. (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the U.S. to which such gain is attributable);

- the non-U.S. holder is a nonresident alien individual present in the U.S. for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- Salarius' common stock or pre-funded warrants constitutes U.S. real property interests ("USRPIs"), by reason of Salarius' status as a U.S. real property holding corporation ("USRPHC), for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, Salarius believes it is not currently and does not anticipate becoming a USRPHC. Because the determination of whether Salarius is a USRPHC depends on the fair market value of Salarius' USRPIs relative to the fair market value of Salarius' other business assets and Salarius' non-U.S. real property interests, however, there can be no assurance Salarius' is not a USRPHC or will not become one in the future. Even if Salarius is or was to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of Salarius' common stock will not be subject to U.S. federal income tax if its common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market such as the Nasdaq Global Market, and such non-U.S. holder owned, actually and constructively, 5% or less of Salarius' common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder's holding period. Special rules may apply to non-U.S. holders of pre-funded warrants, who should consult their tax advisors.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Exercise of Pre-Funded Warrants

As discussed above under the section titled "Description of Pre-Funded Warrants—Exercisability," a non-U.S. holder may exercise the pre-funded warrant by payment of the exercise price or through a cashless exercise. The U.S. federal income tax treatment of a cashless exercise of pre-funded warrants into Salarius' common stock is unclear, and non-U.S. holder's should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of pre-funded warrants. In general, however, a non-U.S. holder should not recognize gain or loss for U.S. federal income tax purposes upon exercise of a pre-funded warrant pursuant to either method, except to the extent such non-U.S. holder receives a cash payment for a fractional share that would otherwise have been issuable upon exercise of the pre-funded warrant, which will be treated as a sale subject to the rules described above under "—Gain on Disposition of Salarius' Common Stock or Pre-Funded Warrants."

The taxation of property received with respect to a pre-funded warrant on exercise other than common shares is unclear. It is possible such a receipt of property would be treated as a distribution as described above, although other treatments may also be possible. Prospective investors should consult their tax advisors regarding the proper treatment of any such receipt of property in respect of the pre-funded warrants on exercise.

Certain Adjustments to the Pre-Funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the pre-funded warrants, or an adjustment to the exercise price of the pre-funded warrants, may be treated as a constructive distribution to a non-U.S. holder of the pre-funded warrants if, and to the extent that, such adjustment has the effect of increasing such non-U.S. holder's proportionate interest in Salarius' "earnings and

profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to Salarius' shareholders).

Information Reporting and Backup Withholding

Subject to the discussion below on FATCA, a non-U.S. holder will not be subject to backup withholding with respect to distributions on Salarius' common stock Salarius makes to the non-U.S. holder, provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a U.S. person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or other applicable certification. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on Salarius' common stock to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Information reporting and backup withholding may apply to the proceeds of a sale or other taxable disposition of Salarius' common stock or pre-funded warrants within the U.S., and information reporting may (although backup withholding generally will not) apply to the proceeds of a sale or other taxable disposition of Salarius' common stock or pre-funded warrants outside the U.S. conducted through certain U.S.-related financial intermediaries, in each case, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder on IRS Form W-8BEN or W-8BEN-E, or other applicable form (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or such owner otherwise establishes an exemption. Proceeds of a disposition of Salarius' common stock or pre-funded warrants conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

FATCA

Withholding taxes may be imposed under the Foreign Account Tax Compliance Act ("FATCA"), on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) paid on Salarius' common stock, to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules, in each case subject to the proposed Treasury Regulations discussed below. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), and annually report certain information about such accounts. Because Salarius may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of these withholding rules Salarius or the applicable withholding agent may treat the entire distribution as a dividend. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of these withholding provisions. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the U.S. governing FATCA may be subject to different rules.

UNDERWRITING

Salarius is offering the securities described in this prospectus through the underwriters named below. Ladenburg Thalmann & Co. Inc. is acting as the representative of the underwriters in this offering. Subject to the terms and conditions of the underwriting agreement, dated as of , 2025, the underwriters have agreed to purchase the number of Salarius' securities set forth opposite its respective name below.

Underwriters	Number of Shares	Number of Pre-Funded Warrants
Ladenburg Thalmann & Co. Inc.		
Total		

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the securities directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of $ per share.

The underwriting agreement provides that the underwriters' obligation to purchase the securities Salarius is offering is subject to conditions contained in the underwriting agreement.

No action has been taken by Salarius or the underwriters that would permit a public offering of the securities in any jurisdiction outside the United States where action for that purpose is required. None of Salarius' securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised Salarius that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by Salarius.

	Per Share[1]	Per Pre-Funded Warrant[1]	Total Without Over-Allotment	Total With Full Over-Allotment
Public offering price	$	$	$	$
Underwriting discounts and commissions [3][4]	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

(1) The public offering price and underwriting discount corresponds to a public offering price per share of common stock of up to $ ($ net of the underwriting discount) and a public offering price per pre-funded warrant of up to $ ($ net of the underwriting discount).

(2) We have also agreed to pay the representative a management fee of 1.0% of the gross proceeds from the offering and to reimburse the accountable expenses of the representative, including a pre-closing expense allowance of up to a maximum of $25,000 and an additional closing expense allowance up to a maximum of $120,000.

(3) We have granted a 45-day option to the underwriters to purchase up to additional shares of common stock at the public offering price per share of common stock set forth above less the underwriting discounts and commissions solely to cover over- allotments, if any.

We estimate the total expenses payable by Salarius for this offering to be approximately $, which amount includes (i) the underwriting discount of $, (ii) reimbursement of the accountable expenses of the underwriters, including the legal fees of the representative, in an amount not to exceed $25,000 for pre-closing expenses plus $120,000 for closing expenses, (iii) a management fee of approximately $ which represents 1.0% of the total gross proceeds payable to the representative and (iv) other estimated company expenses of approximately $, which includes legal, accounting, printing costs, and various fees associated with the registration and listing of Salarius' shares.

Representative Warrants

We have agreed to issue to the representative or its respective designees warrants, or "representative warrants," upon the closing of this offering, which entitle it to purchase up to shares of common stock (or shares of common stock assuming the exercise of the over-allotment option in full). The representative warrants will have an exercise price equal to $ per share of common stock. The representative warrants will be exercisable immediately upon issuance, at any time and from time to time, in whole or in part, during the five-year period commencing from the commencement of sales of this offering. For a more complete description of the representative warrants, please see the form of representative warrant which will be filed as an exhibit to the registration statement of which this prospectus is part. The representative warrants and the shares of common stock underlying the representative warrants are being registered on the registration statement of which this prospectus is a part.

Over-allotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to an additional shares of common stock at the public offering price per share of common stock set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover overallotments, if any, made in connection with this offering. If any additional shares of common stock are purchased, the underwriters will offer these shares of common stock on the same terms as those on which the other securities are being offered.

Determination of Offering Price

Salarius' common stock is currently traded on the Nasdaq Capital Market under the symbol "SLRX." On , 2025, the closing price of Salarius' common stock was $ per share.

The public offering price of the securities offered by this prospectus will be determined by negotiation between Salarius and the underwriters. Among the factors that will be considered in determining the final public offering price:

- Salarius' history and its prospects;
- The industry in which Salarius operates;
- Salarius' past and present operating results; and
- The general condition of the securities markets at this time of this offering.

The public offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities sold in this offering. That price is subject to change as a result of market conditions and other factors and Salarius cannot assure you that the shares of common stock sold in this offering can be resold at or above the public offering price.

Right of First Refusal

Salarius has granted to the representative the right of first refusal for a period of eighteen (18) months following the closing of this offering to act as sole bookrunner, exclusive placement agent or exclusive sales agent or exclusive financial advisor in connection with any financing of Salarius.

Listing

Salarius' shares of common stock are listed on Nasdaq under the symbol "SLRX." The last reported sales price of Salarius' shares of common stock on , 2025 was $ per share. The actual public offering price will be determined between Salarius, the underwriters and the investors in the offering, and may be at a discount to the current market price of Salarius' common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price. There is no established public trading market for the pre-funded warrants, and Salarius does not expect such a market to develop. In addition, Salarius does not intend to apply for listing of the pre-funded warrants on any securities exchange or other trading system.

Lock-up Agreements

Salarius' officers and directors have agreed with the underwriters to be subject to a lock-up period of days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of Salarius' common stock or any securities convertible into, or exercisable or exchangeable for, shares of Salarius' common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. Salarius has also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of its securities for days following the closing of this offering, although Salarius will be permitted to issue stock options or stock awards to directors, officers and employees under its existing plans.

The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Other Relationships

From time to time, certain of the underwriters and their affiliates may provide in the future, various advisory, investment and commercial banking and other services to Salarius in the ordinary course of business, for which they will receive customary fees and commissions. The representative acts as sales agent under the certain At The Market Offering Agreement with Salarius which it has received and may continue to receive cash compensation in connection therewith. The representative will receive a cash commission of $350,000 in connection with advisory services provided to Decoy in connection with the consummation of the Merger and will receive a total number of shares of common stock of the combined company upon consummation of the Merger.

Transfer Agent, Warrant Agent and Registrar

The transfer agent and registrar for Salarius' common stock is Equiniti Trust Company, LLC.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on a website maintained by the underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters that may make Internet distributions on the same basis as other allocations. In connection with the offering, the underwriters or syndicate members may distribute prospectuses electronically.

The underwriters have informed Salarius that they do not expect to confirm sales of shares offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by Salarius or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of Salarius' common stock;

Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of Salarius' securities or preventing or retarding a decline in the market prices of Salarius' securities. As a result the price of Salarius' common stock may be higher than the price that might otherwise exist in the open market. Neither Salarius nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of Salarius' common stock. These transactions may be effected on Nasdaq, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in Salarius' common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of Salarius' common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither Salarius, nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of Salarius' securities. In addition, neither Salarius nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Indemnification

Salarius has agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriters may be required to make for these liabilities.

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for Salarius by Hogan Lovells US LLP. The underwriters are being represented by Ellenoff, Grossman & Schole LLP.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements). We've included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

The financial statements of Decoy at December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, included in the Form S-1 of Salarius Pharmaceuticals, Inc., which is referred to and made a part of this prospectus, have been audited by Fruci & Associates II, PLLC, independent registered public accounting firm, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about Decoy's ability to continue as a going concern as described in Note 1 to the financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

Salarius has filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to Salarius and the securities offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants, including this registration statement that file electronically with the SEC. The address is www.sec.gov.

Salarius is subject to the information and periodic reporting requirements of the Exchange Act. Under the Exchange Act, Salarius will file annual, quarterly and current reports, as well as proxy statements and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection at the website of the SEC referred to above.

UNAUDITED PRO FORMA CONSOLIDATED COMBINED FINANCIAL INFORMATION

The following unaudited pro forma consolidated combined financial information is provided to aid you in your analysis of the financial aspects of the Merger and Financing Transactions and presents the combination of the financial information of Salarius and Decoy adjusted to give effect to the Merger and Financing Transaction, or collectively, the Pro Forma Adjustments. Capitalized terms included but not defined below have the same meaning as defined elsewhere in this filing.

On January 10, 2025, Salarius entered into an Agreement and Plan of Merger (the "Merger Agreement"), by and among Salarius, Decoy Therapeutics MergerSub I, Inc., a Delaware corporation and a wholly owned subsidiary of Salarius ("First Merger Sub"), Decoy Therapeutics MergerSub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Salarius ("Second Merger Sub"), and Decoy. Pursuant to the Merger Agreement, Salarius will merge with Decoy (the "Merger") by causing First Merger Sub to be merged with and into Decoy, with Decoy surviving the merger as a wholly-owned subsidiary of Salarius (the "First Merger"). Immediately following the First Merger, Decoy will merge with and into Second Merger Sub, with Second Merger Sub being the surviving entity. Merger Closing is conditioned upon, among other things, minimum proceeds from an offering of at least $6.0 million (the "Qualified Financing" or "Financing Transaction").

The Merger is structured as a stock-for-stock transaction pursuant to which all of Decoy's outstanding equity interests will be exchanged based on an exchange ratio for consideration of a combination of (a) shares of Salarius' common stock in an amount up to (i) 19.9% of Salarius' total shares outstanding as of January 10, 2025 minus (ii) any shares of Salarius common stock issued in any private placement between January 10, 2025 and the effective time of the First Merger, and (b) shares of Series A preferred stock, which is a newly designated series of preferred stock ("Series A Preferred Stock") that is intended to have economic rights equivalent to the common stock, but with only limited voting rights. The number of shares of common stock to be issued at the closing of the Merger ("Merger Closing") and the number of shares of common stock underlying the Series A Preferred Stock to be issued at Merger Closing is based on an exchange ratio which assumes a base value of $28.0 million for Decoy and $4.6 million for Salarius, subject in each case to adjustment based on the "Parent Cash Amount" and "Company Cash Amount" (each as defined in the Merger Agreement) on the anticipated closing date (which excludes any proceeds raised in in the Qualified Financing).

If the Parent Cash Amount is $0 and the Company Cash Amount is $2.0 million, stockholders of Salarius would own approximately 14.1% of the fully diluted common stock, and stockholders of Decoy would own, or hold rights to acquire, approximately 85.9% of Salarius common stock, in each case calculated on a fully-diluted basis for in-the-money options and warrants (and in each case, prior to taking into account any dilution from the Qualified Financing). The calculation of the exchange ratio under the Merger Agreement and post-closing ownership of Salarius stockholders are subject to adjustment based on an assumed value of Salarius at Merger Closing based on the Parent Cash Amount and Company Cash Amount as of the anticipated closing date. To the extent the Parent Cash Amount falls below $0, Salarius' assumed value would be reduced or increased by $100,000 for every $100,000 below the threshold. To the extent the Company Cash Amount falls below $2.0 million, Decoy's assumed value would be reduced by $100,000 for every 100,00 below the threshold.

The Company has preliminarily determined that the Merger will be accounted for as a reverse asset acquisition with Decoy considered the accounting acquirer. This determination is subject to a number of significant judgment and estimates, including that Decoy is not a variable interest entity due to the preliminary expectation that Decoy will have sufficient equity at risk based on the assumed equity at risk at Closing. This conclusion is subject to change based on the actual equity at risk at Closing. The determination that Decoy is considered the accounting acquirer is based on the expectations that, (i) immediately following the Merger, Decoy's senior management will hold key positions in senior management of the combined organization; and (ii) following subsequent shareholder approval (A) Decoy stockholders will own a substantial majority of the voting rights of the combined organization and (B) Decoy will designate a majority of the members of the board of directors of the combined organization. The transaction is expected to be accounted for as a reverse asset acquisition as Salarius does not meet the definition of a business because at the time of the closing of the acquisition, Salarius is not anticipated to have processes or an organized workforce that significantly contribute to its ability to create outputs, and its fair value is concentrated in IPR&D. Accordingly, for accounting purposes: (i) the Merger will be treated as the equivalent of Decoy issuing

stock to acquire the net assets of Salarius, (ii) the net assets of Salarius will be allocated a portion of the transaction price and recorded based upon their relative fair values in the financial statements at the time of closing, (iii) the reported historical operating results of the combined company prior to the Merger will be those of Decoy and (iv) for periods prior to the transaction, shareholders' equity of the combined company is presented based on the historical equity structure of Salarius.

The following unaudited pro forma consolidated combined balance sheet as of September 30, 2024 combines the historical consolidated balance sheet of Salarius as of September 30, 2024 with the historical balance sheet of Decoy as of September 30, 2024 giving further effect to the Pro Forma Adjustments, as if they had been consummated as of September 30, 2024.

The following unaudited pro forma consolidated combined statements of operations for the year ended December 31, 2023 combine the historical consolidated statement of operations of Salarius for the year ended December 31, 2023 and the historical statements of operations of Decoy for the year ended December 31, 2023, giving effect to the Pro Forma Adjustments as if they had been consummated on January 1, 2023, the beginning of the earliest period presented.

The following unaudited pro forma consolidated combined statements of operations for the nine months ended September 30, 2024 combine the historical consolidated statement of operations of Salarius for the nine months ended September 30, 2024 and the historical statements of operations of Decoy for the nine months ended September 30, 2024, giving effect to the Pro Forma Adjustments as if they had been consummated on January 1, 2023, the beginning of the earliest period presented.

The unaudited pro forma consolidated combined financial statements have been derived from and should be read in connection with:

- the accompanying notes to the unaudited pro forma consolidated combined financial statements;
- the historical unaudited consolidated financial statements of Salarius as of and for the nine months ended September 30, 2024 and the related notes included in this prospectus;
- the historical unaudited financial statements of Decoy as of and for the nine months ended September 30, 2024 and the related notes included in this prospectus;
- the historical audited consolidated financial statements of Salarius as of and for the year ended December 31, 2023 and the related notes included in this prospectus;
- the historical audited financial statements of Decoy as of and for the year ended December 31, 2023 and the related notes included in this prospectus;
- the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations of Salarius," " Management's Discussion and Analysis of Financial Condition and Results of Operations of Decoy," and other financial information relating to Salarius and Decoy.

The unaudited pro forma consolidated combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The accounting for the Merger requires the financial calculation of Salarius' net cash. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing unaudited pro forma consolidated combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the Closing of the Merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma consolidated combined financial information and the combined company's future results of operations and financial position.

The unaudited pro forma combined consolidated financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma consolidated combined financial information is not necessarily indicative of the financial position or results of operations in the future

periods or the result that actually would have been realized had Salarius and Decoy been a combined organization during the specified periods. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited consolidated combined pro forma financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma consolidated combined financial information.

UNAUDITED PRO FORMA CONSOLIDATED COMBINED BALANCE SHEET
AS OF SEPTEMBER 30, 2024

(in thousands)

	Historical						
	Decoy	Salarius	Financing Transaction Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
Asset							
Current assets:							
Cash and cash equivalents	3,199	3,284	6,194	(a)	(1,729)	(b) (f)	10,948
Prepaid expenses and other current assets	182	539	—		—		721
Total Current Assets	3,381	3,823	6,194		(1,729)		11,669
Fixed asset, net	71	—	—		—		71
Other assets	40	36	—		—		76
Total assets	3,492	3,859	$ 6,194		(1,729)		11,816
Liabilities, convertible preferred stock and stockholders' equity (deficit)							
Current liabilities:							
Accounts Payable	837	166	$ —		$ —		1,003
Accrued expenses and other current liabilities	308	440	—		156	(c)	904
Notes payable	—	329	—		—		329
Accrued interest and financing expense	2,377	—	—		(2,377)	(d)	—
Deferred income - grants	3,193	—	—		—		3,193
Shareholder notes payable	118	—	—		(118)	(d)	—
Promissory notes payable	2,151	—	—		(2,151)	(d)	—
Convertible note – seed Tranche A	4,382	—	—		(4,382)	(d)	—
Convertible note - seed	1,093	—	—		(1,093)	(d)	—
Convertible note - senior	6,746	—	—		(6,746)	(d)	—
Total Current Liabilities	21,205	935	—		(16,711)		5,429
Warrants	305	—	—		(305)	(d)	—
Total liabilities	21,510	935	—		(17,016)		5,429
Stockholders' equity (deficit):							
Salarius preferred stock; $0.0001 par value;	—	—	—		1	(e)	1
Decoy common stock, $0.00001 par value	1	—	—		(1)	(e)	—
Salarius common stock	—	—	1		—	(d) (e)	1
Additional paid-in capital	293	83,384	6,193	(a)	(63,968)	(d) (e) (f)	25,902
Accumulated deficit	(18,312)	(80,460)	—		79,255	(b) (c) (f)	(19,517)
Total stockholders' equity (deficit)	(18,018)	2,924	6,194		15,287		6,387
Total liabilities, convertible preferred stock and stockholders' equity	3,492	3,859	$ 6,194		(1,729)		11,816

See accompanying notes to the unaudited pro forma combined financial statements

UNAUDITED PRO FORMA CONSOLIDATED COMBINED STATEMENT OF OPERATIONS
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

(in thousands, except share and per share data)

	Historical		Financing Transaction Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
	Decoy	Salarius					
Operating expenses:							
Research and development	1,925	595	—		—		2,520
General and administrative	872	3,651	—		—		4,523
Total operating expenses	2,797	4,246	—		—		7,043
Operating loss	(2,797)	(4,246)	—		—		(7,043)
Other income (expense), net:							
Interest income (expense)	(1,010)	134	—		1,010	(g)	134
Grant income	1,135	—	—		—		1,135
Fair value adjustments on convertible notes payable	(406)	—	—		406	(g)	—
Warrant liability expense	(175)	—			175	(g)	—
Unrealized loss	(1)	—	—		—		(1)
Total other income (expense), net	(457)	134	—		1,591		1,268
Net Income (loss)	$ (3,254)	$ (4,112)	—		1,591		$ (5,775)
Net profit (loss) per share							
Basic	$ (2.53)	$ (5.13)					$ (0.51)
Diluted	$ (2.53)	$ (5.13)					$ (0.51)
Weighted average number of common shares outstanding							
Basic	1,287,930	801,395				(k)	11,372,840
Diluted	1,287,930	801,395				(k)	11,372,840

See accompanying notes to the unaudited pro forma combined financial statements

UNAUDITED PRO FORMA CONSOLIDATED COMBINED STATEMENT OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2023

(in thousands, except share and per share data)

	Historical						
	Decoy	Salarius	Financing Transaction Adjustments	Note 4	Transaction Accounting Adjustments	Note 4	Pro Forma Combined Total
Operating expenses:							
Research and development	1,065	7,174	—		—		8,239
General and administrative	2,385	5,721	—		1,335	(h)	9,441
Impairment of IPR&D	—	—	—		1,205	(i)	1,205
Total operating expenses	3,450	12,895	—		254		18,885
Operating loss	(3,450)	(12,895)	—		$ (2,540)		(18,885)
Other income (expense), net:							
Interest income (expense)	(1,153)	352	—		1,153	(g)	352
Grant income	666	—	—		—		666
Fair value adjustments on convertible notes payable	(5,643)	—			5,643	(g)	—
Warrant liability income	251	—	—		(251)	(g)	—
Total other income (expense), net	(5,879)	352	—		6,545		1,018
Net Income (loss)	(9,329)	$ (12,543)	$ —		$ 4,005		$ (17,867)
Net profit (loss) per share							
Basic	$ (7.24)	$ (30.74)					(1.65)
Diluted	$ (7.24)	$ (30.74)					(1.65)
Weighted average number of common shares outstanding							
Basic	1,287,930	408,078				(j)	10,979,523
Diluted	1,287,930	408,078				(j)	10,979,523

See accompanying notes to the unaudited pro forma combined financial statements

NOTES TO THE UNAUDITED PRO FORMA CONSOLIDATED COMBINED FINANCIAL INFORMATION

1. Description of the Transactions

The Merger

On January 10, 2025, Salarius entered into an Agreement and Plan of Merger (the "Merger Agreement"), by and among Salarius, Decoy Therapeutics MergerSub I, Inc., a Delaware corporation and a wholly owned subsidiary of Salarius ("First Merger Sub"), Decoy Therapeutics MergerSub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Salarius ("Second Merger Sub"), and Decoy. Pursuant to the Merger Agreement, Salarius will merge with Decoy (the "Merger") by causing First Merger Sub to be merged with and into Decoy, with Decoy surviving the merger as a wholly-owned subsidiary of Salarius (the "First Merger"). Immediately following the First Merger, Decoy will merge with and into Second Merger Sub, with Second Merger Sub being the surviving entity. Merger Closing is conditioned upon, among other things, minimum proceeds from an offering of at least $6.0 million (the "Qualified Financing").

The Merger is structured as a stock-for-stock transaction pursuant to which all of Decoy's outstanding equity interests will be exchanged based on an exchange ratio for consideration of a combination of (a) shares of Salarius' common stock in an amount up to (i) 19.9% of Salarius' total shares outstanding as of January 10, 2025 *minus* (ii) any shares of Salarius common stock issued in any private placement between January 10, 2025 and the effective time of the First Merger, and (b) shares of Series A preferred stock, which is a newly designated series of preferred stock ("Series A Preferred Stock") that is intended to have economic rights equivalent to the common stock, but with only limited voting rights. The number of shares of common stock to be issued at the closing of the Merger ("Merger Closing") and the number of shares of common stock underlying the Series A Preferred Stock to be issued at Merger Closing is based on an exchange ratio which assumes a base value of $28.0 million for Decoy and $4.6 million for Salarius, subject in each case to adjustment based on the "Parent Cash Amount" and "Company Cash Amount" (each as defined in the Merger Agreement) on the anticipated closing date (which excludes any proceeds raised in in the Qualified Financing).

If the Parent Cash Amount is $0 and the Company Cash Amount is $2.0 million, stockholders of Salarius would own approximately 14.1% of the fully diluted common stock, and stockholders of Decoy would own, or hold rights to acquire, approximately 85.9% of Salarius common stock, in each case calculated on a fully-diluted basis for in-the-money options and warrants (and in each case, prior to taking into account any dilution from the Qualified Financing). The calculation of the exchange ratio under the Merger Agreement and post-closing ownership of Salarius stockholders are subject to adjustment based on an assumed value of Salarius at Merger Closing based on the Parent Cash Amount and Company Cash Amount as of the anticipated closing date. To the extent the Parent Cash Amount falls below $0, Salarius' assumed value would be reduced or increased by $100,000 for every $100,000 below the threshold. To the extent the Company Cash Amount falls below $2.0 million, Decoy's assumed value would be reduced by $100,000 for every $100,000 below the threshold.

The Company has preliminarily determined that the merger will be accounted for as a reverse asset acquisition with Decoy considered the accounting acquirer. This determination is subject to a number of significant judgment and estimates, including that Decoy is not a variable interest entity due to the preliminary expectation that Decoy will have sufficient equity at risk based on the assumed equity at risk at closing. This conclusion is subject to change based on the actual equity at risk at closing. The determination that Decoy is considered the accounting acquirer is based on the expectations that, (i) immediately following the merger, Decoy's senior management will hold key positions in senior management of the combined organization; and (ii) following subsequent shareholder approval (A) Decoy stockholders will own a substantial majority of the voting rights of the combined organization and (B) Decoy will designate a majority of the members of the board of directors of the combined organization. The transaction is expected to be accounted for as a reverse asset acquisition as Salarius does not meet the definition of a business because at the time of the closing of the acquisition, Salarius is not anticipated to have processes or an organized workforce that significantly contribute to its ability to create outputs, and its fair value is concentrated in IPR&D. Accordingly, for accounting purposes: (i) the merger will be treated as the equivalent of Decoy issuing stock to acquire the net assets of Salarius, (ii) the net assets of Salarius will be allocated a portion of the transaction

price and recorded based upon their relative fair values in the financial statements at the time of closing, (iii) the reported historical operating results of the combined company prior to the merger will be those of Decoy and (iv) for periods prior to the transaction, shareholders' equity of the combined company is presented based on the historical equity structure of Salarius.

2. Basis of Pro Forma Presentation

The unaudited pro forma consolidated combined financial information was prepared pursuant to the rules and regulations of Article 11 of Regulation S-X. The unaudited pro forma consolidated combined balance sheet as of September 30, 2024 was prepared using the historical balance sheets of Salarius and Decoy as of September 30, 2024, and gives effect to the Merger and the Financing Transaction as if they occurred on September 30, 2024. The unaudited pro forma consolidated combined statement of operations for the nine months ended September 30, 2024, and for the year ended December 31, 2023, were prepared using the historical statements of operations of Salarius and Decoy for the nine months ended September 30, 2024 and for the year ended December 31, 2023, respectively, and gives effect to the Merger and the Financing Transaction as if they occurred on January 1, 2023.

The merger is expected to be accounted for as a reverse asset acquisition in accordance with GAAP. Decoy will be deemed to be the accounting acquirer for financial reporting purposes. Accordingly, for accounting purposes: (i) the merger will be treated as the equivalent of Decoy issuing stock to acquire the net assets of Salarius, (ii) the net assets of Salarius will be allocated a portion of the transaction price and recorded based upon their relative fair values in the financial statements at the time of closing, (iii) the reported historical operating results of the combined company prior to the merger will be those of Decoy and (iv) for periods prior to the transaction, shareholders' equity of the combined company is presented based on the historical equity structure of Salarius.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. During preparation of the unaudited pro forma consolidated combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma combined financial information assumes no material differences in accounting policies. Following the Merger and the Financing Transactions, management will conduct a final review of Salarius accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Salarius results of operations or reclassification of assets or liabilities to conform to Decoy's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on this unaudited pro forma consolidated combined financial information.

Decoy and Salarius may incur significant costs associated with integrating their operations after the Merger is completed. The unaudited pro forma combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies, which may result from the Merger.

To the extent that there are significant changes to the business following completion of the Merger, the assumptions and estimates set forth in the unaudited pro forma consolidated financial information could change significantly. Accordingly, the pro forma adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted following the completion of the Merger. There can be no assurances that these additional analyses will not result in material changes to the estimates of fair value.

Additionally, as described in Note 1, the Pro Forma Assumptions include assumed terms for each of the Financing Transactions that may vary significantly from the actual terms of each.

3. Preliminary Estimated Purchase Price

For purposes of these unaudited pro forma combined financial information, the total estimated purchase price is summarized as follows:

		Shares
Estimated number of common shares of the combined company to be owned by Salarius stockholders[(1)]		1,441,288
Multiplied by the fair value per share of Decoy common stock[(2)]	$	1.80
Estimated fair value per share of Salarius common stock		2,594,583
Estimated Decoy transaction costs[(3)]		200,000
Estimated purchase price		2,794,583

(1) The final purchase price will be determined based on the number of Salarius common shares outstanding as of the closing date of the Merger. For purposes of this unaudited pro forma consolidated combined financial information, the estimated number of shares is based on the sum of the 1,441,157 shares of Salarius common stock outstanding as of September 30, 2024 and the 131 restricted stock units expected to convert to common shares as a result of the Merger.

(2) The estimated purchase price was based on the closing price of Salarius common stock as reported on the Nasdaq Capital Market on January 6, 2025. The fair value of the consideration given based on Salarius' stock price is more clearly evident, and thus, more reliably measurable, than the fair value of the net assets acquired, as Salarius' stock price is measured using Level 1 fair value inputs. The alternative treatment under US GAAP of measuring the purchase consideration using the fair value of the net assets acquired would require using a combination of Level 1, 2 and 3 fair value inputs and is not more clearly evident and more reliably measurable.

(3) The estimated transaction costs incurred by Decoy is based on estimates as of January 6, 2025. As indicated in ASC 805-50 regarding asset acquisitions, the accounting acquirer's transaction costs incurred directly related to the asset purchase should be included in the consideration to acquire the assets.

The net assets of Salarius as of September 30, 2024 are $2.9 million. After giving effect to the estimated transaction costs expected to be incurred by Salarius of $1.3 million, the net assets prior to allocation of the purchase price to the assets acquired will be $1.6 million. The excess of the purchase price of $2.8 million over the $1.6 million of net assets at close of $1.2 million will be allocated to IPR&D, which will be expensed immediately following the closing of the Merger.

The estimated purchase consideration reflected in this unaudited pro forma combined financial information does not purport to represent what the actual purchase consideration will be when the merger is completed. A 10% increase or decrease in the stock price would change the purchase price by approximately $0.3 million and result in a related change to the amount of IPR&D expensed in the merger. The actual purchase price will fluctuate until the effective time of the merger.

4. Shares of Salarius Common Stock Issued to Decoy's Stockholders Upon Closing of the Merger

At the effective time of the Merger, based on (i) the assumed exchange ratio of 2.2853 shares of Salarius common stock for each share of Decoy common stock, (ii) capitalization as of September 30, 2024, and (iii) assumptions for the Financing Transaction set forth in Note 1 above, Salarius would expect to issue 286,790 shares of common stock and the remaining 6,808,781 equivalent shares in the form of 6,809 shares of Series A preferred stock to the stockholders of Decoy in the Merger, determined as follows:

	Shares
Decoy shares of common stock outstanding	1,287,930
Decoy convertible notes equivalent shares	1,816,945
Total Decoy common stock equivalent shares	3,104,875
Exchange ratio	2.2853
Estimated total shares of Salarius common stock and common stock-equivalent preferred stock shares to be issued to Decoy stockholders upon closing of the Merger	7,095,571

5. Pro Forma Adjustments

Adjustments included in the column under the heading "Transaction Accounting Adjustments" are primarily based on information contained within the Merger Agreement. Adjustments included in the column under the heading "Financing Adjustments" are primarily based on assumptions associated with the Qualified Financing. Further analysis will be performed upon completion of the Merger to confirm these estimates.

Based on a review of Salarius' summary of significant accounting policies, the nature and amount of any adjustments to the historical consolidated financial statements of Salarius to conform to the accounting policies of Decoy are not expected to be significant.

Both Decoy and Salarius have a history of generating net operating losses and maintain a full valuation allowance against their net deferred tax assets. As a result, both entities have not reflected an income tax benefit or expense within the historical financial statement periods presented.

Management has not identified any changes to the income tax positions due to the Merger that would result in an incremental tax expense or benefit. Accordingly, no tax-related adjustments have been reflected for the pro forma adjustments.

The pro forma adjustments, based on preliminary estimates that may change significantly as additional information is obtained, are as follows:

(a) To reflect $5.7 million in net proceeds to be received pursuant to the Qualified Financing ($6.0 million) in exchange for the issuance of 3,333,333 shares of Salarius common stock, offset by $0.3 million in transaction costs associated with the Qualified Financing and $0.5 million in net proceeds to be received for the issuance of 142,410 shares of Salarius common stock pursuant to the SPA financing.

(b) To reflect the estimated payment of $1.2 million in transaction costs to be incurred by Salarius, $0.2 million in transaction costs to be incurred by Decoy, and the redemption of the Salarius equity-classified warrants for $0.4 million in connection with the Merger. The $1.2 million in transaction costs to be incurred by Salarius is reflected as an offset to accumulated deficit, the $0.2 million in transaction costs to be incurred by Decoy will be capitalized into the acquired IPR&D asset and then expensed and offset to accumulated deficit due to the IPR&D asset having no alternative future use, and the $0.4 million paid to redeem the Salarius equity-classified warrants will be offset against additional paid-in capital.

(c) To reflect the Salarius' estimated compensation expense of $0.2 million related to transaction bonuses negotiated as a result of the impending Merger. As such, the transaction bonuses will be accrued and recorded as general and administrative expense in the pro forma statement of operations for the year ended December 31, 2023 and as an offset to accumulated deficit within the unaudited pro forma combined balance sheet as of September 30, 2024.

(d) To reflect the exchange of the Decoy warrants, shareholder notes, promissory notes, convertible notes, and their associated accrued interest into 1,815,945 shares of Decoy common stock which will then be converted into shares of Salarius common stock and common stock-equivalent Salarius Series A preferred stock shares based on the exchange ratio.

(e) To reflect the exchange of 3,104,875 shares of Decoy common stock for shares of Salarius common stock and common stock-equivalent Salarius Series A preferred stock shares.

(f) To reflect the reclassification of historical accumulated deficit of Salarius into additional paid-in capital, offset by the write-off of the IPR&D asset acquired in the Merger of $1.2 million, the $1.2 million of estimated Salarius transaction costs, and the $0.2 million of transaction bonuses.

(g) See table below for total equity impact.

(h) To reflect the reversal of interest expense and fair value adjustments associated with the warrants, shareholder notes, promissory notes, and convertible notes during the periods ended September 30, 2024

and December 31, 2024 that will be converted to shares of Salarius common stock upon closing of the Merger.

(i) To reflect the recognition of non-recurring general and administrative expense associated with the $1.2 million of transaction costs to be incurred by Salarius and the $0.2 million of transaction bonuses to be recorded in the pro forma statement of operations for the year ended December 31, 2023.

(j) To reflect the recognition of the non-recurring impairment of the $1.2 million IPR&D asset acquired as part of the reverse asset acquisition because it has no alternative future use in the pro forma statement of operations for the year ended December 31, 2023.

(k) The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net income (loss) for the nine months ended September 30, 2024, and the year ended December 31, 2023. In addition, the number of shares used to calculate the pro forma combined basic and diluted net income (loss) per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding at the Merger Closing, including the shares to be issued in the Qualified Financing, as if they have been outstanding for the entirety of the periods presented. For the nine months ended September 30, 2024, and the year ended December 31, 2023, the pro forma weighted average shares outstanding has been calculated as follows:

	September 30, 2024	December 31, 2023
Weighted-average Decoy common shares outstanding – basic and diluted	1,287,930	1,287,930
Decoy convertible notes equivalent shares	1,816,945	1,816,945
Total	3,104,875	3,104,875
Application of exchange ratio	2.2853	2.2853
Adjusted Weighted-average Decoy common shares equivalents outstanding – basic and diluted	7,095,571	7,095,571
$6.0 million of Qualified Financing	3,333,333	3,333,333
$0.5 million of SPA Financing	142,410	142,410
Weighted-average Salarius common shares outstanding	801,395	408,078
Conversion of Salarius RSUs to Salarius common shares	131	131
Pro forma combined weighted average number of shares of common stock – basic and diluted	11,372,840	10,979,523

(l) The total impact to equity for the above adjustments are reflected in the table below:

(in thousands, except share data)	Preferred Stock		Common Stock				Amount Paid-in-Capital	Accumulated Deficit	Stockholders' equity
	Salarius		Decoy		Salarius				
	Shares	Amount	Shares	Amount	Shares	Amount			
Exchange of Decoy warrants, shareholder notes, promissory notes, convertible notes, and their associated accrued interest into shares of Decoy common stock (d)	—	$ —	1,816,945	$ —	—	$ —	$ 17,173	$ —	$ 17,173
Salarius Financing Transaction (a)	—	—	—	—	3,333,333	1	5,669	—	5,700
Salarius SPA Financing (a)	—	—	—	—	142,410	—	494	—	494
Salarius transaction costs (b) (c)	—	—	—	—	—	—	—	(1,335)	(1,335)
Elimination of Salarius' historical equity carrying value (f)	—	—	—	—	(1,441,288)	—	(83,384)	81,795	(1,589)
Exchange of outstanding Decoy common stock into Salrius common stock based on the assumed Exhange Ratio (e)	6,809	1	(3,104,875)	(1)	286,790	—	—	—	—
Reverse asset acquisition (b)	—	—	—	—	1,441,288	—	2,594	—	2,594
Expense IPR&D acquired in reverse asset acquisition (f)	—	—	—	—	—	—	—	(1,205)	(1,205)
Redemption of equity-classified Salarius warrants (b)	—	—	—	—	—	—	(350)	—	(350)
Total Adjustment	6,809	$ 1	(1,287,930)	$ (1)	3,762,534	$ 1	(57,774)	$ 79,255	$ 21,482

INDEX TO FINANCIAL STATEMENTS

Salarius Pharmaceuticals, Inc.

Decoy Therapeutics Inc.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Salarius Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Salarius Pharmaceuticals, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has a lack of revenue from product sales and has suffered recurring losses from operations since its inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Accrued Research and Development Expenses

Description of the Matter	During 2023, the Company recognized $7.1 million of research and development expenses and recorded accrued clinical trial expenses of $0.4 million as of December 31, 2023. As described in Note 2 to the consolidated financial statements, the Company records accruals for estimated costs of research and development activities that include contract services for clinical trials. Clinical trial activities performed by third parties are accrued and expensed based upon management's assessment of the status of each clinical trial and the work completed per patient. Auditing the Company's accounting for accrued third-party clinical trial research and development expenses is especially challenging because of the judgment applied by management to determine the progress or stage of completion of the activities under the Company's research and development agreements and the cost and extent of work performed during the reporting period for services not yet billed by contracted third-party vendors.
How We Addressed the Matter in Our Audit	Our audit procedures included, among others, testing the accuracy and completeness of the underlying inputs used in management's analysis to determine costs incurred, inspecting invoices received from third parties, and clerically testing the accrual calculation. To test the significant inputs, we corroborated the patient enrollment, length of treatment, trial timeline and progress of research and development activities through discussion with the Company's research and development personnel that oversee the research and development projects, inspected the terms and conditions of the Company's contracts with third parties, and obtained external confirmation of key inputs to the accrual calculation, such as amounts invoiced and the number and timing of patients enrolled in clinical studies. We also reviewed subsequent disbursements for payments made to third parties after the balance sheet date to evaluate the completeness of the research and development expenses recognized.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2019.

Houston, Texas

March 22, 2024, except for the effects of the reverse stock split as described in Note 1, as to which the date is January 21, 2025

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 5,899,910	$ 12,106,435
Grants receivable from CPRIT	—	1,610,490
Prepaid expenses and other current assets	619,763	803,373
Total current assets	6,519,673	14,520,298
Other assets	66,850	130,501
Total assets	$ 6,586,523	$ 14,650,799
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 602,853	$ 2,858,330
Accrued expenses and other current liabilities	406,745	1,407,861
Notes payable	289,643	$ —
Total liabilities	$ 1,299,241	$ 4,266,191
Commitments and contingencies (NOTE 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; none issued or outstanding	—	$ —
Common stock, $0.0001 par value; 100,000,000 shares authorized; 492,304 and 281,987shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively[(1)]	49	$ 28
Additional paid-in capital	81,635,074	$ 74,189,728
Accumulated deficit	(76,347,841)	$ (63,805,148)
Total stockholders' equity	5,287,282	$ 10,384,608
Total liabilities and stockholders' equity	$ 6,586,523	$ 14,650,799

(1) Share and per share amounts have been recast to reflect the 1-for-8 reverse stock split effected on June 14, 2024 on retroactive basis for all periods presented.

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Twelve Months Ended December 31	
	2023	**2022**
Operating expenses:		
Research and development	7,173,747	15,836,828
General and administrative	5,721,197	7,138,403
Loss on impairment of goodwill	—	8,865,909
Total operating expenses	12,894,944	31,841,140
Loss before other income (expense)	(12,894,944)	(31,841,140)
Change in fair value of warrant liability	—	14,454
Interest income	352,251	218,730
Net loss	$ (12,542,693)	$ (31,607,956)
Loss attributable to common stockholders	$ (12,542,693)	$ (31,607,956)
Loss per common share — basic and diluted[(1)]	$ (30.74)	$ (119.02)
Total net loss per share	$ (30.74)	$ (119.02)
Weighted-average number of common shares outstanding — basic and diluted	408,078	265,564

(1) Share and per share amounts have been recast to reflect the 1-for-8 reverse stock split effected on June 14, 2024 on retroactive basis for all periods presented.

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Twelve Months Ended December 31	
	2023	2022
Operating activities		
Net loss	$ (12,542,693)	$ (31,607,956)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and impairment	10,051	6,677
Loss on Impairment of goodwill	—	8,865,909
Equity-based compensation expense	524,838	796,803
Grant receivable writeoff	130,000	
Change in fair value of warrant liability	—	(14,454)
In-process research and development technology	—	1,987,900
Changes in operating assets and liabilities:		
Grants receivable	1,480,490	—
Prepaid expenses and other current assets	807,770	202,538
Accounts payable	(2,255,477)	1,312,735
Accrued expenses and other current liabilities	(1,001,116)	854,527
Net cash (used in) operating activities	(12,846,137)	(17,595,321)
Investing activities		
Purchase in-process research and development technology	—	(1,500,000)
Net cash used in investing activities	—	(1,500,000)
Financing activities		
Proceeds from issuance of equity securities	6,920,529	1,987,376
Payments on note payable	(280,917)	—
Net cash provided by financing activities	6,639,612	1,987,376
Net decrease in cash, cash equivalents and restricted cash	(6,206,525)	(17,107,945)
Cash, cash equivalents and restricted cash at beginning of period	12,106,435	29,214,380
Cash, cash equivalents and restricted cash at end of period	$ 5,899,910	$ 12,106,435
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 14,754	$ —
Non-cash investing and financing activities:		
Common stock issued for in-process research and development technology		$ 487,900
Accrued cost for shares issued for cash		$ 2,500
Insurance premium financed by note payable	$ 570,560	

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock [1]		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2021	**226,199**	**$ 23**	**$ 70,920,154**	**$ (32,197,192)**	**$ 38,722,985**
Common Stock issued for in-process research and development technology	5,000	—	487,900	—	487,900
Issuance of equity securities, net	46,697	5	1,984,871	—	1,984,876
Equity-based compensation expense	3,491	—	768,255	—	768,255
Issuance of equity securities for services	600	—	28,548	—	28,548
Net loss	—	—	—	(31,607,956)	(31,607,956)
Balance at December 31, 2022	**281,987**	**$ 28**	**$ 74,189,728**	**$ (63,805,148)**	**$ 10,384,608**
Issuance of equity securities, net	201,580	20	6,920,509		6,920,529
Equity-based compensation expense	8,737	1	524,837		524,838
Net loss				(12,542,693)	(12,542,693)
Balance at December 31, 2023	**492,304**	**$ 49**	**$ 81,635,074**	**$ (76,347,841)**	**$ 5,287,282**

(1) Share and per share amounts have been recast to reflect the 1-for-8 reverse stock split effected in June 14, 2024 on retroactive basis for all periods presented.

See accompanying notes to consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND OPERATIONS

Nature of Business

Salarius Pharmaceuticals, Inc. ("Salarius" or the "Company"), together with its subsidiaries, Salarius Pharmaceuticals, LLC, Flex Innovation Group LLC, and TK Pharma, Inc., is a clinical-stage biopharmaceutical company focused on developing effective treatments for cancers with high, unmet medical need. Specifically, the Company is focused on treatments for cancers caused by dysregulated gene expression, i.e., genes that are incorrectly turned on or off. The Company is focused on two classes of drugs that address gene dysregulation: targeted protein inhibitors and targeted protein degraders. The Company's technologies have the potential to work in both liquid and solid tumors. The Company's current pipeline consists of two small molecule drugs: 1) SP-3164, a targeted protein degrader, and 2) seclidemstat (SP-2577), a targeted protein inhibitor. The Company is located in Houston, Texas.

Going Concern

Salarius has no products approved for commercial sale, has not generated any revenue from product sales to date and has suffered recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements are prepared using accounting principles generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. Salarius will require substantial additional capital to fund its research and development expenses related to its pipeline including SP-3164 and seclidemstat. Based on Salarius' expected cash requirements, Salarius believes that there is substantial doubt that its existing cash and cash equivalents, will be sufficient to fund its operations through one year from the financial statements' issuance date. The Company may attempt to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and may also consider new collaborations or selectively partnering its technology. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans.

Although the Company is currently exploring various strategic alternatives, these strategic alternatives may not be successful in the next several months prior to its cash position getting to the point that it will need to pursue the winding down and dissolution of the Company. If the Company does not raise capital or successfully engage a strategic partner before the first half of 2025, it will be forced to cease operations, liquidate assets and possibly seek bankruptcy protection or engage in a similar process.

Reverse Stock Splits

On June 14, 2024, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-8 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "Reverse Stock Split") which became effective as of June 14, 2024. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

On October 14, 2022, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a 1-for-25 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "Reverse Stock Split") which became effective as of October 14, 2022. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The Company considered its going concern disclosure requirements in accordance with ASC 205-40-50.The Company has performed an analysis and concluded substantial doubt exists with respect to the Company being able to continue as a going concern through one year from the date of issuance of the consolidated financial statements for the year ended December 31, 2023.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America as defined by the FASB ASC requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Cash and Cash Equivalents

Salarius considers all highly-liquid investments with original maturities of three months or less to be cash equivalents.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no impairment charges related to long-lived assets during the twelve months ended December 31, 2023 and 2022.

Goodwill

Goodwill is not amortized, but is tested at least annually for impairment at the reporting unit level. The Company has determined that the reporting unit is the single operating segment disclosed in its current financial statements. Additional impairment assessments may be performed on an interim basis if the Company encounters events or changes in circumstances that would indicate that, more likely than not, the carrying value of goodwill has been impaired.

Impairment is the condition that exists when the carrying amount of goodwill exceeds its implied fair value. The Company utilizes the option to perform a qualitative assessment for its reporting unit and if the Company concludes it is more likely than not that the fair value of the reporting unit is less than its carrying amount, then the Company utilizes the two-step quantitative assessment. The Company's qualitative assessment is sensitive to assumptions related to potential adverse events and circumstances, including current market trends in control premiums and involves judgement in determining comparable peer companies to include in the control premium evaluation. The Company recorded a goodwill impairment loss of $8.9 million during the twelve months ended December 31, 2022. There was no goodwill balance as of December 31, 2023 and 2022.

Financial Instruments and Credit Risks

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and restricted cash. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation ("FDIC"). Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

Warrants

The Company determines whether warrants should be classified as a liability or equity. For warrants classified as liabilities, the Company estimates the fair value of the warrants at each reporting period using Level 3 inputs with changes in fair value recorded in the Consolidated Statement of Operations within change in fair value of warrant liability. The estimates in valuation models are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the fair value of the common stock underlying the warrants, and could differ materially in the future. The Company will continue to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable warrant. For warrants classified as equity contracts, the Company allocates the transaction proceeds to the warrants and any other free-standing instruments issued in the transaction based on an allowable allocation method.

Clinical Trial Accruals

The Company's preclinical and clinical trials are performed by third party contract research organizations (CROs) and/or clinical investigators, and clinical supplies are manufactured by contract manufacturing organizations (CMOs). Invoicing from these third parties may be monthly based upon services performed or based upon milestones achieved. The Company accrues these expenses based upon its assessment of the status of each clinical trial and the work completed, and upon information obtained from the CROs and CMOs. The Company's estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CMOs regarding the status and cost of the studies, and may not match the actual services performed by the organizations. This could result in adjustments to the Company's research and development expenses in future periods. To date the Company has had no significant adjustments.

Grants Receivable and Revenue Recognition

Salarius' source of revenue has been from a grant received from CPRIT. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. The Company records revenue and a corresponding grants receivable when qualifying costs are incurred before the grants are received. The Company's CPRIT grant expired during 2023 and no additional amounts are expected to be recognized or received.

Research and Development Costs

Research and development costs consist of expenses incurred in performing research and development activities, including pre-clinical studies and clinical trials. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, the costs of laboratory equipment and facilities, license fees and other external costs. Research and development costs are expensed when incurred.

Costs incurred in obtaining IPRD that has no alternative future use are charged to research and development expense as acquired, and presented as investing activity cash outflows on the Statement of Cash Flow.

Equity-Based Compensation

Salarius measures equity-based compensation based on the grant date fair value of the awards and recognizes the associated expense in the financial statements over the requisite service period of the award, which is generally the vesting period.

The Company uses the Black-Scholes option valuation model to estimate the fair value of the stock-based compensation and incentive units. Assumptions utilized in these models include expected volatility calculated based on implied volatility from traded stocks of peer companies, dividend yield and risk-free interest rate. Additionally, forfeitures are accounted for in compensation cost as they occur.

Loss Per Share

Basic net loss per share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods, as the inclusion of all potential common shares outstanding is anti-dilutive.

The number of anti-dilutive shares, consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, (iii) unvested restricted stock and (iv) rights entitling holders to receive warrants to purchase the Company's common shares, which have been excluded from the computation of diluted loss per share, was 1,366,892 and 88,080 shares as of December 31, 2023 and 2022, respectively.

Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore, a valuation allowance has been established for the full amount of the deferred tax assets.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2023 and 2022, the Company did not have any significant uncertain tax positions and no interest or penalties have been charged. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company is subject to routine audits by taxing jurisdictions.

Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which is intended to improve the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid by jurisdiction. The ASU is effective for public business entities for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements.

Recently Adopted Accounting Standard

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement of all expected credit losses for financial assets including trade receivables held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments - Credit Losses. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also

subsequently issued ASU No. 2019-04, Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 825), which did not change the core principle of the guidance in ASU 2016-13, but clarified that expected recoveries of amounts previously written off and expected to be written off should be included in the valuation account and should not exceed amounts previously written off and expected to be written off. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities, excluding smaller reporting companies. Early adoption is permitted. As a smaller reporting company, the guidance was effective for the Company on January 1, 2023. The adoption of this standard did not have a material impact to this Company's consolidated financial statements.

NOTE 3. GRANTS RECEIVABLE

Grants receivable represents qualifying costs incurred where there is reasonable assurance that conditions of the grant have been met but the corresponding funds have not been received as of the reporting date. Grants receivable balances were $0 as of December 31, 2023 and $1.6 million at December 31, 2022, respectively. The Company received $1.5 million from the Cancer Prevention and Research Institute of Texas on February 15, 2023.

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2023 and 2022 consisted of the following:

	December 31,	
	2023	2022
Prepaid clinical trial expenses	$ —	$ 11,185
Prepaid insurance	468,495	624,612
Other prepaid and current assets	151,268	167,576
Total prepaid expenses and other current assets	$ 619,763	$ 803,373

Prepaid insurance is mainly comprised of prepaid directors' and officers' insurance. In July 2023, the Company financed its directors and officers' insurance premium with a short term note the principal amount of which is approximately $0.6 million bearing interest at a rate of 7.87%. The note payable balance, which was included within Current Liabilities on the Consolidated Balance Sheet was $ 0.3 million as of December 31, 2023.

NOTE 5. COMMITMENTS AND CONTINGENCIES

Cancer Prevention and Research Institute of Texas

In June 2016, the Company entered into a Cancer Research Grant Contract with CPRIT. Pursuant to the contract, CPRIT awarded the Company a grant up to $18.7 million, further modified to $16.1 million to fund development of LSD 1 inhibitor. The grant expired during 2023.

The Company will retain ownership over any intellectual property developed under the contract ("Project Result"). With respect to non-commercial use of any Project Result, the Company agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes.

The Company is obligated to make revenue-sharing payments to CPRIT with respect to net sales of any product covered by the contract, up to a maximum repayment of certain percentage of the aggregate amount paid to the Company by CPRIT under the CPRIT contract. The payments are determined as a percentage of net sales, which may be reduced if the Company is required to obtain a license from a third party to sell any such product. In addition, upon meeting the foregoing limitation on revenue-sharing payments, the Company agreed to make continued revenue-sharing payments to CPRIT of less than 1% of net sales.

License Agreement with the University of Utah Research Foundation

In 2011, the Company entered into a license agreement with the University of Utah, under which, the Company acquired license to LSD 1. In exchange for the license, the Company issued 2% equity ownership in the Company based on a fully diluted basis at the effective date of the agreement and subject to certain adjustments specified in the agreement, granted revenue sharing rights on any resulting products or processes to commence on first commercial sale, and milestone payments based upon regulatory approval of any resulting product or process as well as on the second anniversary of first commercial sale.

Lease Agreement

The Company presently leases office space under operating lease agreements on a month to month basis.

6. FAIR VALUE OF FINANCIAL INSTRUMENTS

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, are used to measure fair value:

Level 1-Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3-Significant unobservable inputs including Salarius' own assumptions in determining fair value.

The Company believes the recorded values of its financial instruments, including cash and cash equivalents, accounts payable and note payable approximate their fair values due to the short-term nature of these instruments.

7. STOCKHOLDERS' EQUITY

Common Stock Issuances

On February 5, 2021, the Company entered into an At the Market Offering Agreement ("ATM") with Ladenburg Thalmann & Co. Inc. Under this agreement the Company is able to issue and sell, from time to time, shares of its common stock. On February 5, 2021 and July 2, 2021, the Company filed prospectus supplements with the SEC to register the offering and sale of Common Stock having an aggregate offering price of up to $6.3 million and $25.0 million, respectively. During the twelve months ended December 31, 2023, the Company sold 87,034 shares of common stock under the At the Market Offering Agreement with gross proceeds of $1.7 million.

On May 11, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an accredited investor (the "Investor"), pursuant to which the Company agreed to issue and sell to the Investor in a private placement (the "Offering") (i) 41,250 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 413,296 shares of Common Stock, (iii) Series A-1 warrants (the "Series A-1 Warrants") to purchase up to 454,546 shares of Common Stock and (iv) Series A-2 warrants (the "Series A-2 Warrants") and together with the Series A-1 Warrants, the "Common Stock Warrants," and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 454,546 shares of Common Stock, at a purchase price of (a) $13.2 per Share and accompanying Common Stock Warrants and (b) $13.1992 per Pre-Funded Warrant and accompanying Common Stock Warrants. The aggregate gross proceeds from the Offering were approximately $6.0 million, exclusive of placement agent fees and expenses and other offering expenses. The Offering closed on May 16, 2023.

During the twelve months ended December 31, 2023, the Company issued 73,296 shares of its Common Stock upon the exercise of Pre-Funded Warrants.

On January 12, 2022, the Company issued 5,000 shares of the Company's common stock, valued at $0.5 million to purchase in-process research and development technology SP-3164.

On April 22, 2022, the Company entered into a securities purchase agreement with certain institutional and accredited investors for the sale by the Company of approximately 46,697 shares of the Company's common stock, par value $0.0001 per share (the "Common Stock") at a purchase price of $50 per share. Concurrently, the Company also sold unregistered warrants exercisable for an aggregate of approximately 35,023 shares of Common Stock,

which represents 75% of the shares of Common Stock sold, with an exercise price of $ 67.98 per share. The transaction closed on April 26, 2022 with gross proceeds of $2.3 million before deducting certain fees due to the placement agent and other estimated transaction expenses.

Warrants Exercised for Cash

The Company has five-year warrants outstanding that were issued in February 2020 and subsequently modified in December 2020 in connection with the issuance of additional inducement warrants. The warrants are exercisable at a price per share of $230. The inducement warrants expire on June 11, 2026, and are exercisable at a price per share of $236.40. The Company has 35,023 warrants outstanding that were issued in April 2022, with an exercise price of $67.98 per share. The warrants were exercisable six months following the issuance date and will expire five and one-half years from the issuance date. During the twelve months ended December 31, 2023 and 2022, no warrants were exercised.

In May 2023, the Company issued Series A-1 Warrants that are exercisable for a period of five and one-half (5.5) years from the issuance date at an exercise price of $11.20 per share. Series A-2 Warrants are exercisable for a period of eighteen (18) months from the issuance date at an exercise price of $11.20 per share. Each Pre-Funded Warrant was sold in lieu of shares of Common Stock, are exercisable immediately upon issuance, have an exercise price of $0.0001 per share and expire when exercised in full. During the twelve months ended December 31, 2023, no Series A-1 or A-2 warrants were exercised.

In connection with the above mentioned Offering, the Company issued warrants to its exclusive placement agency H.C Wainwright & Co., LLC to purchase up to 31,818 shares of common stock at an exercise price per share of $16.50 and a term of five and one-half (5.5) years. During the twelve months ended December 31, 2023, no warrants were exercised.

As of December 31, 2023 and 2022, approximately 1,355,598 (340,000 are Pre-Funded Warrants) and 74,689 warrants remain outstanding, respectively.

The terms of the outstanding warrants require the Company, upon the consummation of any fundamental transaction to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume the Company's obligations under the warrants and the associated transaction documents. In addition, holders of warrants are entitled to participate in any fundamental transaction on an as-converted or as-exercised basis, which could result in the holders of the Company's common stock receiving a lesser portion of the consideration from a fundamental transaction. The terms of the warrants could also impede the Company's ability to enter into certain transactions or obtain additional financing in the future.

8. EQUITY-BASED COMPENSATION

Equity Incentive Plans

The Company has granted options to employees, directors, and consultants under the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance-based stock awards and other stock-based awards. Additionally, the 2015 Plan provides for the grant of performance-based cash awards. ISOs may be granted only to the Company's employees. All other awards may be granted to the Company's employees, including officers, and to non-employee directors and consultants. As of December 31, 2023 and 2022, there were 10,542 and 5,904 shares, respectively, remaining available for the grant of stock option under the 2015 Plan.

During the twelve months ended December 31, 2023 and 2022, the Company awarded 0 and 6,420, respectively, stock options to its employees and directors, pursuant to the plan described above. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Expected volatilities utilized in the model are based on implied volatilities from traded stocks of peer companies. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields.

The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. The fair value of the option grants of $0.5 million has been estimated with the following assumptions for the year ended December 31, 2022:

	2022
Risk-free interest rate	1.62%-1.70%
Volatility	125.19% - 126.42%
Expected life (years)	5 -6 years
Expected dividend yield	0.00 %

The following table summarizes stock option activity for employees and non-employees for the twelve months ended December 31, 2023 and 2022:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding at December 31, 2021	7,990	$ 550	8.50
Granted	6,420	88	
Exercised	—	—	
Forfeited	(847)	—	
Expired	(172)	—	
Outstanding at December 31, 2022	13,391	$ 189	8.29
Exercisable at December 31, 2022	4,763	$ 287	7.63
Granted	—	$ —	
Exercised	—		
Forfeited	(2,228)		
Expired	—		
Outstanding at December 31, 2023	11,163	$ 190	7.26
Exercisable at December 31, 2023	8,448	$ 212	7.13

As of December 31, 2023 and 2022, there was approximately $0.3 million and $0.8 million of total unrecognized compensation cost, respectively, related to unvested stock options. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 1.11 years.

9. INCOME TAX

The Company has no current or deferred tax expense due to its current year loss and its overall net operating loss position. A reconciliation of the federal statutory tax rate and the effective tax rates for the year ended December 31, 2023 and 2022 is as follows:

	December 31	
	2023	2022
Federal Tax at Statutory Rate	21.00 %	21.00 %
Permanent	(0.89)%	(6.25)%
Change in Valuation Allowance	(22.77)%	(21.73)%
True Ups	— %	(0.06)%
R&D Credit	2.66 %	7.04 %
Effective Tax Rate	— %	— %

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets were as follows:

	December 31	
	2023	2022
Capitalized R&D Expenses	$ 5,610,221	$ 5,199,721
Other Deferred Items	44,193	145,935
Stock Compensation	455,192	484,205
Net Operating Loss - US	6,161,916	3,919,323
R&D Credits	3,627,377	3,293,572
Net deferred tax assets	15,898,899	13,042,756
Valuation Allowance	(15,898,899)	(13,042,756)
Net deferred tax assets (liabilities)	**$ —**	**$ —**

The valuation allowance recorded by the Company as of December 31, 2023 and December 31, 2022 resulted from the uncertainties of the future utilization of deferred tax assets relating from NOL carry forwards for federal and state income tax purposes. Realization of the NOL carry forwards is contingent on future taxable earnings. The deferred tax asset was reviewed for expected utilization using a “more likely than not” approach by assessing the available positive and negative evidence surrounding its recoverability. Accordingly, a full valuation allowance continues to be recorded against the Company’s deferred tax asset, as it was determined based upon past and projected future losses that it was “more likely than not” that the Company’s deferred tax assets would not be realized. In future years, if the deferred tax assets are determined by management to be “more likely than not” to be realized, the recognized tax benefits relating to the reversal of the valuation allowance will be recorded. The Company will continue to assess and evaluate strategies that will enable the deferred tax asset, or portion thereof, to be utilized, and will reduce the valuation allowance appropriately as such time when it is determined that the “more likely than not” criteria is satisfied.

The federal net operating loss carryforwards of $29.3 million have an indefinite life, but the R&D credits of $3.4 million begin to expire in 2039. Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company’s net operating loss carry forwards could be subject to annual limitations against taxable income in future periods, which could substantially limit the eventual utilization of such carry forwards. The Company has not analyzed the historical or potential impact of its equity financings on beneficial ownership and therefore no determination has been made whether the net operating loss carry forward is subject to any Internal

Revenue Code Section 382 limitation. To the extent there is a limitation, there could be a reduction in the deferred tax asset with an offsetting reduction in the valuation allowance.

Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold, as well as accrued interest and penalties, if any, would be recorded as a interest and penalties expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2023.

10. SUBSEQUENT EVENTS

On March 15, 2024, the Company filed a preliminary proxy statement with the SEC in connection with a special meeting of stockholders will be held on May 9, 2024. The business for the meeting is to consider and vote to approve an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of the Company's outstanding shares of common stock at a ratio in the rage of 1:4 to 1:8.

SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2024 (Unaudited)	December 31, 2023 (Audited)
Assets		
Current assets:		
Cash and cash equivalents	$ 3,284,029	$ 5,899,910
Prepaid expenses and other current assets	538,617	619,763
Total current assets	3,822,646	6,519,673
Other assets	36,518	66,850
Total assets	**$ 3,859,164**	**$ 6,586,523**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 165,801	$ 602,853
Accrued expenses and other current liabilities	439,931	406,745
Notes payable	328,849	289,643
Total liabilities	934,581	1,299,241
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; 0 issued and outstanding	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized; 1,441,157 and 492,304 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	144	49
Additional paid-in capital	83,384,124	81,635,074
Accumulated deficit	(80,459,685)	(76,347,841)
Total stockholders' equity	2,924,583	5,287,282
Total liabilities and stockholders' equity	**$ 3,859,164**	**$ 6,586,523**

See accompanying notes to condensed consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30		Nine Months Ended September 30	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 137,234	$ 1,036,354	$ 594,683	$ 7,113,794
General and administrative	869,237	1,495,831	3,650,920	4,810,449
Total operating expenses	1,006,471	2,532,185	4,245,603	11,924,243
Loss before other income (expense)	(1,006,471)	(2,532,185)	(4,245,603)	(11,924,243)
Interest income, net and other	34,350	89,369	133,759	263,346
Loss from continuing operations	**(972,121)**	**(2,442,816)**	**(4,111,844)**	**(11,660,897)**
Net loss	**$ (972,121)**	**$ (2,442,816)**	**$ (4,111,844)**	**$ (11,660,897)**
Loss per common share — basic and diluted [1]	**$ (0.76)**	**$ (5.21)**	**$ (5.13)**	**$ (30.71)**
Weighted-average number of common shares outstanding — basic and diluted [1]	1,281,869	469,254	801,395	379,693

(1) Share and per share amounts have been restated to reflect the 1-for-8 reverse stock split effected in June 14, 2024 on retroactive basis for all periods presented.

See accompanying notes to condensed consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30	
	2024	**2023**
Operating activities		
Net loss	$ (4,111,844)	$ (11,660,897)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,318	8,946
Equity-based compensation expense	222,685	439,462
Grant receivable write-off	—	130,000
Changes in operating assets and liabilities:		
Grants receivable	—	1,480,490
Prepaid expenses and other assets	506,888	671,848
Accounts payable	(437,052)	(1,769,690)
Accrued expenses and other current liabilities	33,186	(635,067)
Net cash used in operating activities	(3,782,819)	(11,334,908)
Financing activities		
Proceeds from issuance of equity securities, net	1,526,460	6,920,530
Payments on note payable	(359,522)	(111,469)
Net cash (used in) provided by financing activities	1,166,938	6,809,061
Net decrease in cash, cash equivalents and restricted cash	(2,615,881)	(4,525,847)
Cash, cash equivalents and restricted cash at beginning of period	5,899,910	12,106,435
Cash, cash equivalents and restricted cash at end of period	$ 3,284,029	$ 7,580,588
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Cash paid for interest	$ 12,064	$ 6,799
Accrued issuance costs for issuance of equity securities	$ —	$ —
Insurance premium financed by note payable	$ 398,728	$ 570,560

See accompanying notes to condensed consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock [1]		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	**281,987**	**$ 28**	**$ 74,189,728**	**$ (63,805,148)**	**$ 10,384,608**
Issuance of equity securities, net	17,812	2	311,679	—	311,681
Equity-based compensation expense	8,737	1	203,344	—	203,345
Net loss	—	—	—	(5,340,773)	(5,340,773)
Balance at March 31, 2023	**308,536**	**$ 31**	**$ 74,704,751**	**$ (69,145,921)**	**$ 5,558,861**
Issuance of equity securities, net	110,472	11	6,608,779	—	6,608,790
Equity-based compensation expense	—	—	123,459	—	123,459
Net loss	—	—	—	(3,877,308)	(3,877,308)
Balance at June 30, 2023	**419,008**	**$ 42**	**$ 81,436,989**	**$ (73,023,229)**	**$ 8,413,802**
Issuance of equity securities, net	73,296	7	52	—	59
Equity-based compensation expense	—	—	112,658	—	112,658
Net loss	—	—	—	(2,442,816)	(2,442,816)
Balance at September 30, 2023	**492,304**	**$ 49**	**$ 81,549,699**	**$ (75,466,045)**	**$ 6,083,703**
Balance at December 31, 2023	**492,304**	**$ 49**	**$ 81,635,074**	**$ (76,347,841)**	**$ 5,287,282**
Issuance of equity securities, net	47,000	5	33	—	38
Equity-based compensation expense	—	—	77,508	—	77,508
Net loss	—	—	—	(1,715,290)	(1,715,290)
Balance at March 31, 2024	**539,304**	**$ 54**	**$ 81,712,615**	**$ (78,063,131)**	**$ 3,649,538**
Issuance of equity securities and other, net	101,873	10	65,070	—	65,080
Equity-based compensation expense	—	—	85,168	—	85,168
Net loss	—	—	—	(1,424,433)	(1,424,433)
Balance at June 30, 2024	**641,177**	**$ 64**	**$ 81,862,853**	**$ (79,487,564)**	**$ 2,375,353**
Issuance of equity securities, net	799,980	80	1,461,262	—	1,461,342
Equity-based compensation expense	—	—	60,009	—	60,009
Net loss	—	—	—	(972,121)	(972,121)
Balance at September 30, 2024	**1,441,157**	**$ 144**	**$ 83,384,124**	**$ (80,459,685)**	**$ 2,924,583**

(1) Share and per share amounts have been restated to reflect the 1-for-8 reverse stock split effected in June 14, 2024 on retroactive basis for all periods presented.

See accompanying notes to condensed consolidated financial statements.

SALARIUS PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1. ORGANIZATION AND OPERATIONS

Nature of Business

Salarius Pharmaceuticals, Inc. ("Salarius" or the "Company"), together with its subsidiaries, Salarius Pharmaceuticals, LLC, Flex Innovation Group LLC, and TK Pharma, Inc., is a clinical-stage biopharmaceutical company focused on developing effective treatments for cancers with high, unmet medical need. Specifically, the Company is concentrated on developing treatments for cancers caused by dysregulated gene expression, i.e., genes that are incorrectly turned on or off. The Company has two classes of drugs that address gene dysregulation: targeted protein inhibitors and targeted protein degraders. The Company's technologies have the potential to work in both liquid and solid tumors. The Company' current pipeline consists of two small molecule drugs: 1) SP-3164, a targeted protein degrader, and 2) seclidemstat (SP-2577), a targeted protein inhibitor. The Company is located in Houston, Texas. On August 8, 2023, the Company announced that it retained Canaccord Genuity, LLC to lead a comprehensive review of strategic alternatives focusing on maximizing stockholder value, including but not limited to, an acquisition, merger, reverse merger, divestiture of assets, licensing, or other strategic transactions involving the Company. In connection with the evaluation of strategic alternatives and in order to extend Company resources, the Company implemented multiple cost-savings plans to extend the Company's expected cash runway into the first half of 2025.

Going Concern

Salarius has no products approved for commercial sale, has not generated any revenue from product sales to date and has suffered recurring losses from operations since its inception. The lack of revenue from product sales to date and recurring losses from operations since its inception raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements are prepared using accounting principles generally accepted in the United States applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. Based on Salarius' expected cash requirements, Salarius believes that there is substantial doubt that its existing cash and cash equivalents, will be sufficient to fund its operations through one year from the financial statements' issuance date. The Company may attempt to obtain additional capital through the sale of equity securities in one or more offerings or through issuances of debt instruments, and may also consider new collaborations or selectively partnering its technology. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans.

Although the Company is currently exploring various strategic alternatives, these strategic alternatives may not be successful in the next several months prior to its cash position getting to the point that it will need to pursue the winding down and dissolution of the Company. If the Company does not raise capital or successfully engage a strategic partner before the first half of 2025, it will be forced to cease operations, liquidate assets and possibly seek bankruptcy protection or engage in a similar process.

Reverse Stock Splits

On June 14, 2024, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-8 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "Reverse Stock Split") which became effective as of June 14, 2024. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

On October 14, 2022, the Company filed a Certificate of Amendment to the Company's restated certificate of incorporation with the Secretary of State of the State of Delaware to effect a 1-for-25 reverse stock split of the Company's issued and outstanding shares of common stock, par value $0.0001 per share (the "Reverse Stock Split")

which became effective as of October 14, 2022. All historical share and per share amounts reflected throughout this report have been adjusted to reflect the Reverse Stock Split.

NOTE 2. BASIS OF PRESENTATION AND SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standard Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying interim financial statements are unaudited. These unaudited interim financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. These unaudited interim financial statements should be read in conjunction with the audited financial statements and accompanying notes for the year ended December 31, 2023 included elsewhere in the Company's Annual Report on Form 10-K filed with the SEC on March 22, 2024, as amended on April 22, 2024. In the opinion of management, the unaudited interim financial statements reflect all the adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2024 and the results of operations for the three and nine months ended September 30, 2024 and 2023. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The December 31, 2023 balance sheet included herein was derived from the audited financial statements, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America as defined by the FASB ASC requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Cash and Cash Equivalents

Salarius considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

Financial Instruments and Credit Risks

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and restricted cash. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation. Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

Warrants

The Company determines whether warrants should be classified as a liability or equity. For warrants classified as liabilities, the Company estimates the fair value of the warrants at each reporting period using Level 3 inputs with changes in fair value recorded in the Condensed Consolidated Statement of Operations within change in fair value of warrant liability. The estimates in valuation models are based, in part, on subjective assumptions, including but not limited to stock price volatility, the expected life of the warrants, the risk-free interest rate and the fair value of the

common stock underlying the warrants, and could differ materially in the future. The Company will continue to adjust the fair value of the warrant liability at the end of each reporting period for changes in fair value from the prior period until the earlier of the exercise or expiration of the applicable warrant. For warrants classified as equity contracts, the Company allocates the transaction proceeds to the warrants and any other free-standing instruments issued in the transaction based on an allowable allocation method.

Clinical Trial Accruals

The Company's preclinical and clinical trials are performed by third party contract research organizations ("CROs") and/or clinical investigators, and clinical supplies are manufactured by contract manufacturing organizations ("CMOs"). Invoicing from these third parties may be monthly based upon services performed or based upon milestones achieved. The Company accrues these expenses based upon its assessment of the status of each clinical trial and the work completed, and upon information obtained from the CROs and CMOs. The Company's estimates are dependent upon the timeliness and accuracy of data provided by the CROs and CMOs regarding the status and cost of the studies, and may not match the actual services performed by the organizations. This could result in adjustments to the Company's research and development expenses in future periods. To date the Company has had no significant adjustments.

Grants Receivable and Revenue

Salarius' source of revenue had been from a grant received from CPRIT. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred. Final reimbursement from the grant was received in the first quarter of 2024. The Company's CPRIT grant expired during 2023 and no additional amounts are expected to be recognized or received.

Research and Development Costs

Research and development costs consist of expenses incurred in performing research and development activities, including pre-clinical studies and clinical trials. Research and development costs include salaries and personnel-related costs, consulting fees, fees paid for contract research services, the costs of laboratory equipment and facilities, license fees and other external costs. Research and development costs are expensed when incurred.

Equity-Based Compensation

Salarius measures equity-based compensation based on the grant date fair value of the awards and recognizes the associated expense in the financial statements over the requisite service period of the award, which is generally the vesting period.

The Company uses the Black-Scholes option valuation model to estimate the fair value of stock options granted to employees and directors. Assumptions utilized in these models including expected volatility calculated based on implied volatility from traded stocks of peer companies, dividend yield and risk-free interest rate. Additionally, forfeitures are accounted for in compensation cost as they occur. Restricted stock and restricted stock units granted to employees and directors are measured at fair value based upon the closing price of the Company's common stock on the grant date.

Loss Per Share

Basic net loss per share is calculated by dividing the net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Since the Company was in a loss position for all periods presented, diluted net loss per share is the same as basic net loss per share for all periods, as the inclusion of all potential common shares outstanding is anti-dilutive.

The number of anti-dilutive shares, consisting of common shares underlying (i) common stock options, (ii) stock purchase warrants, (iii) rights entitling holders to receive warrants to purchase the Company's common shares,

and (iv) restricted stock units which have been excluded from the computation of diluted loss per share, was approximately 1,047,070 and 1,370,516 shares as of September 30, 2024 and 2023, respectively.

Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial reporting and the tax reporting basis of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax assets will be realized. The Company has evaluated available evidence and concluded that the Company may not realize the benefit of its deferred tax assets; therefore, a valuation allowance has been established for the full amount of the deferred tax assets.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of September 30, 2024 and December 31, 2023, the Company did not have any significant uncertain tax positions and no interest or penalties have been charged. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company is subject to routine audits by taxing jurisdictions.

NOTE 3. GRANT RECEIVABLE FROM CPRIT

Grants receivable balances are zero at September 30, 2024 and December 31, 2023. During the nine months ended September 30, 2024 and 2023, the Company received $0.1 million and $1.5 million from CPRIT, respectively. Since inception, the Company has received approximately $16.1 million under the grant. The grant was closed in 2023.

NOTE 4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at September 30, 2024 and December 31, 2023 consisted of the following:

	September 30, 2024	December 31, 2023
Insurance	$ 419,602	$ 468,495
Other prepaid and current assets	119,015	151,268
Total prepaid expenses and other current assets	$ 538,617	$ 619,763

Insurance is mainly comprised of prepaid directors' and officers' insurance. In July 2024, the Company financed its directors and officers' insurance premium with a short term note, the principal amount of which is approximately $0.4 million bearing interest at a rate of 9.74%. The note payable balance, which was included within Current Liabilities on the Condensed Consolidated Balance Sheet was $0.3 million at both September 30, 2024 and December 31, 2023.

NOTE 5. COMMITMENTS AND CONTINGENCIES

Cancer Prevention and Research Institute of Texas

In June 2016, the Company entered into a Cancer Research Grant Contract with CPRIT. Pursuant to the contract, CPRIT awarded the Company a grant up to $18.7 million, further modified to $16.1 million to fund development of LSD 1 inhibitor. The grant expired in 2023.

The Company will retain ownership over any intellectual property developed under the contract ("Project Result"). With respect to non-commercial use of any Project Result, the Company agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license with right to sublicense any necessary additional intellectual property rights to exploit all Project Results by CPRIT, other governmental entities and agencies of the State of Texas, and private or independent institutions of higher education located in Texas, for education, research and other non-commercial purposes.

The Company is obligated to make revenue-sharing payments to CPRIT with respect to net sales of any product covered by the contract, up to a maximum repayment of certain percentage of the aggregate amount paid to the Company by CPRIT under the CPRIT contract. The payments are determined as a percentage of net sales, which may be reduced if the Company is required to obtain a license from a third party to sell any such product. In addition, upon meeting the foregoing limitation on revenue-sharing payments, the Company agreed to make continued revenue-sharing payments to CPRIT of less than 1% of net sales.

License Agreement with the University of Utah Research Foundation

In 2011, the Company entered into a license agreement with the University of Utah, under which the Company acquired an exclusive license to an epigenetic enzyme lysine specific demethylase 1 ("LSD1"). In exchange for the license, the Company issued 2% equity ownership in the Company on a fully diluted basis at the effective date of the agreement subject to certain adjustments specified in the agreement, such as granted revenue sharing rights on any resulting products or processes to commence on first commercial sale, and milestone payments based upon regulatory approval of any resulting product or process as well as on the second anniversary of first commercial sale.

Lease Agreement

The Company presently leases office space under operating lease agreements on a month-to-month basis.

NOTE 6. FAIR VALUE OF FINANCIAL INSTRUMENTS

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, are used to measure fair value:

Level 1 - Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Significant unobservable inputs including Salarius' own assumptions in determining fair value.

The Company believes the recorded values of its financial instruments, including cash and cash equivalents, accounts payable and note payable approximate their fair values due to the short-term nature of these instruments.

NOTE 7. STOCKHOLDERS' EQUITY

Common Stock - Issuances

During the nine months ended September 30, 2024 and September 30, 2023, the Company sold 608,949 and 87,034 shares of common stock in an "at the market offering" ("ATM") with gross proceeds of $1.7 million and $1.7 million, respectively.

On May 11, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an accredited investor (the "Investor"), pursuant to which the Company agreed to issue and sell to the Investor in a

private placement (the "Offering") (i) 41,250 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 413,296 shares of Common Stock, (iii) Series A-1 warrants (the "Series A-1 Warrants") to purchase up to 454,546 shares of Common Stock and (iv) Series A-2 warrants (the "Series A-2 Warrants") and together with the Series A-1 Warrants, the "Common Stock Warrants," and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 454,546 shares of Common Stock, at a purchase price of (a) $13.20 per Share and accompanying Common Stock Warrants and (b) $13.1992 per Pre-Funded Warrant and accompanying Common Stock Warrants. The aggregate gross proceeds from the Offering were approximately $6.0 million, exclusive of placement agent fees and expenses and other offering expenses. The Offering closed on May 16, 2023.

During the nine months ended September 30, 2024 and September 30, 2023 , the Company issued 340,000 and 73,296 shares of its Common Stock upon the exercise of Pre-Funded Warrants.

Warrants Exercisable for Cash

The Company has five-year (5) warrants outstanding that were issued in February 2020 and subsequently modified in December 2020 in connection with the issuance of additional inducement warrants. The warrants are exercisable at a price per share of $230.00. The inducement warrants expire on June 11, 2026, and are exercisable at a price per share of $236.40. The Company has five-and-one-half-year (5.5) year warrants outstanding that were issued in April 2022, with an exercise price of $67.98 per share. The warrants became exercisable six months following the issuance date and will expire five and one-half years from the issuance date.

The Company's Series A-1 Warrants are exercisable for a period of five and one-half (5.5) years from the issuance date at an exercise price of $11.20 per share, expiring on November 16, 2028. Series A-2 Warrants expired on November 18, 2024. Each Pre-Funded Warrant was sold in lieu of shares of Common Stock, are exercisable immediately upon issuance, have an exercise price of $0.0008 per share and expire when exercised in full. At September 30, 2024, there were zero Pre- Funded Warrants outstanding.

In connection with the above mentioned Offering, the Company issued warrants to representatives to purchase up to 31,818 shares of common stock at an exercise price per share of $16.50 and a term of five and one-half (5.5) years.

As of September 30, 2024 and 2023, approximately 1,015,385 and 1,355,600 warrants remain outstanding (0 and 340,000 are Pre-Funded Warrants), respectively.

The terms of the outstanding warrants require the Company, upon the consummation of any fundamental transaction to, among other obligations, cause any successor entity resulting from the fundamental transaction to assume the Company's obligations under the warrants and the associated transaction documents. In addition, holders of warrants are entitled to participate in any fundamental transaction on an as-converted or as-exercised basis, which could result in the holders of the Company's common stock receiving a lesser portion of the consideration from a fundamental transaction. In addition, certain of our outstanding warrants provide that, in the event of a fundamental transaction that is approved by our board of directors, the holders of such warrants have the option to require us to pay to such holders an amount of cash equal to the Black-Scholes value of the warrants. Such amount could be significantly more than the warrant holders would otherwise receive if they were to exercise their warrants and receive the same consideration as the other holders of common stock, which in turn could reduce the consideration that holders of common stock would be concurrently entitled to receive in such fundamental transaction. The terms of the warrants could also impede the Company's ability to enter into certain transactions or obtain additional financing in the future.

NOTE 8. EQUITY-BASED COMPENSATION

Equity Incentive Plans

The Company has granted options to employees, directors, and consultants under the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance-based stock awards

and other stock-based awards. Additionally, the 2015 Plan provides for the grant of performance-based cash awards. ISOs may be granted only to the Company's employees. All other awards may be granted to the Company's employees, including officers, and to non-employee directors and consultants. As of September 30, 2024, there were approximately 9,844 shares remaining available for grant awards under the 2015 Plan.

During the nine-month periods ended September 30, 2024 and 2023, the Company awarded 21,125 and 0 stock options to its employees and directors, pursuant to the plan described above. Stock options generally vest over one to four years and have a contractual term of ten years. Stock options are valued using the Black-Scholes option pricing model and compensation cost is recognized based on the resulting value over the service period. Expected volatilities utilized in the model are based on implied volatilities from traded stocks of peer companies. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. The fair value of the option grants awarded during the nine - month period ended September 30, 2024 was $0.1 million, which has been estimated with the following assumptions on the grant date.

	Nine Months Ended September 30 2024
Risk-free interest rate	4.25%-4.61%
Volatility	106.07% - 123.31%
Expected life (years)	5.00-6.00
Expected dividend yield	0 %

During the nine months ended September 30, 2023, the Company awarded 1,525 restricted stock units to its employees and 4,580 restricted stock awards to its officers and directors, pursuant to the plan described above. Both the restricted stock units and restricted stock awards are valued at the closing price $12.56 of the Company's common stock on the grant date, and generally vest over one to four years. Total fair value of the restricted stock awards and restricted stock units awarded during the nine - month period ended September 30, 2023 is $76,679.

The following table summarizes stock option activity for employees and non-employees for the nine months ended September 30, 2024 and 2023:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding at December 31, 2022	13,391	$ 189.36	8.29
Granted	—		
Exercised	—		
Forfeited	—		
Expired	—		
Outstanding at September 30, 2023	13,391	$ 189.36	7.54
Exercisable at September 30, 2023	8,893	$ 226.40	7.36
Outstanding at December 31, 2023	11,164	$ 190.24	7.26
Granted	21,125	$ 3.02	
Exercised	—		
Forfeited	735		
Expired	—		
Outstanding at September 30, 2024	31,554	$ 66.75	8.45
Exercisable at September 30, 2024	9,086	$ 206.48	6.41

As of September 30, 2024 and 2023, there was approximately $0.1 million and $0.4 million, respectively, of total unrecognized compensation cost related to unvested stock options. Total unrecognized compensation cost will be adjusted for future changes in employee and non-employee forfeitures, if any. The Company expects to recognize that cost over a remaining weighted-average period of 0.75 years.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Decoy Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Decoy Therapeutics, Inc. ("the Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations, shareholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has generated an accumulated deficit of $15.1 million since its inception. Until the Company is successful in gaining regulatory approvals, it is unable to sell the Company's product in any market. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Grant Income

As stated in Note 3 in financial statements, the Company has received grants from two funding sources. The grant amounts are considered significant to the overall financial statements and requires auditor subjectivity and judgment to assess the appropriate guidance to which these transactions apply, as well as significant auditor effort to test the appropriateness of deferred grant income released to income during the periods.

How the Critical Audit Matter Was Addressed in the Audit

Our principal audit procedures to evaluate management's analysis of revenue recognition on grants consisted of the following, among others:

1. Obtained and analyzed grant agreements and other supporting documents to identify potential provisions that would significantly impact the manner in which the related income could be recognized.

2. Performed GAAP analysis to determine grant related income was being recognized pursuant to the appropriate guidance.

3. Tested selections of expenses asserted to be related to specific grants to determine that deferred grant funds released to income were appropriately recorded.

/s/ Fruci & Associates II, PLLC
Fruci & Associates II, PLLC – PCAOB ID #05525
We have served as the Company's auditor since 2024.

Spokane, Washington
November 26, 2024

DECOY THERAPEUTICS, INC.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,156,433	$ 1,624,242
Prepaid expenses and other current assets	194,664	65,864
Total current assets	4,351,097	$ 1,690,106
Fixed assets, net of depreciation	105,450	140,758
Other assets - long term	41,000	40,280
Total assets	$ 4,497,547	$ 1,871,144
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 400,495	$ 434,462
Accrued expenses	185,024	59,501
Accrued interest and financing expense	1,541,863	408,257
Deferred income - grants	4,077,453	143,654
Promissory note	1,425,939	—
Convertible note - seed tranche A	4,122,000	1,381,000
Convertible note - seed	1,073,000	749,000
Convertible note - senior	6,523,556	4,038,000
Total current liabilities	19,349,330	7,213,874
Warrants	131,000	382,000
Total liabilities	$ 19,480,330	$ 7,595,874
Commitments and contingencies	—	—
Shareholders' equity:		
Preferred stock; par value $0.001 par value – 2,000,000 shares authorized -0- shares issued and outstanding at December 31, 2023 and 2022.	—	—
Common stock; par value $.001 per share; 6,000,000 shares authorized (includes 1,000,000 non-voting shares) at December 31, 2023 and 2022; 1,287,930 shares issued and outstanding at December 31, 2023 and 2022.	1,288	1,288
Additional paid in capital	74,512	4,026
Accumulated deficit	(15,058,583)	(5,730,044)
Total shareholders' equity (deficit)	$ (14,982,783)	$ (5,724,730)
Total liabilities and shareholders' equity	$ 4,497,547	$ 1,871,144

The accompanying footnotes are an integral part of these consolidated financial statements

DECOY THERAPEUTICS, INC.
Consolidated Statements of Operations

	Years Ended December 31,	
	2023	2022
Operating expenses		
General and administrative	$ 1,065,022	$ 1,024,835
Research and development	2,384,897	2,265,601
Total operating expenses	$ 3,449,919	$ 3,290,436
Other (income) and expenses		
Grant income	$ (666,201)	$ (738,990)
Fair value adjustment to convertible notes payable	5,643,000	703,000
Warrant liability (income) expense	(251,000)	108,000
Financing expense	52,556	22,500
Unrealized loss (gain)	—	(315)
Interest and financing expense	1,100,265	331,011
Total other (income) expense	5,878,620	425,206
Net loss	$ (9,328,539)	$ (3,715,643)
Net loss attributable to shareholders - per share		
Basic	$ (7.24)	$ (2.56)
Fully-diluted	$ (7.24)	$ (2.56)
Weighted average number of common shares		
Basic	1,287,930	1,449,292
Fully-diluted	1,287,930	1,449,292

The accompanying footnotes are an integral part of these consolidated financial statements

DECOY THERAPEUTICS, INC.
Consolidated Statements of Shareholders' Equity
Years Ended December 31, 2023 and 2022

	Preferred Shares		Common Shares				
	Shares	Amount	Shares	Amount	Additional Paid in	Accumulated Deficit	Total
Balance at December 31, 2021	—	$ —	1,500,000	$ 1,500	$ 3,659	$ (2,014,402)	$ (2,009,243)
Sale of common stock	—	—	3,930	4	47	—	51
Purchase of common stock	—	—	(216,000)	(216)	—	—	(216)
Stock based compensation	—	—	—	—	320	—	320
Net loss	—	—	—	—	—	(3,715,643)	(3,715,643)
Balance at December 31, 2022	—	$ —	1,287,930	$ 1,288	$ 4,026	$ (5,730,045)	$ (5,724,731)
Stock based compensation	—	—	—	—	70,486	—	70,486
Net loss	—	—	—	—	—	(9,328,539)	(9,328,539)
Balance at December 31, 2023	—	$ —	1,287,930	$ 1,288	$ 74,512	$ (15,058,584)	$ (14,982,784)

The accompanying footnotes are an integral part of these consolidated financial statements

DECOY THERAPEUTICS, INC.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2023	2022
Cash flows used in operating activities:		
Net loss	$ (9,328,539)	$ (3,715,643)
Depreciation and amorization	96,533	39,840
Fair value adjustment to convertible notes payable	5,643,000	703,000
Change in fair value of warrant liability	(251,000)	108,000
Stock based compensation	70,486	320
Non-cash interest expense related to notes	1,133,605	366,011
Changes in assets and liabilities:		
Increase in prepaid expenses & other assets	(129,520)	(98,045)
Increase in accounts payable and accrued expenses	91,556	203,699
Increase (decrease) in deferred revenue - grants	3,933,799	(314,746)
Net cash used in operating activities	$ 1,259,921	$ (2,707,565)
Cash flows provided by (used in) investing activities:		
Purchase of property, plant and equiptment	$ (8,669)	$ (158,098)
Net cash provided by (used in) investing activities	$ (8,669)	$ (158,098)
Cash flows provided by financing activities:		
Proceeds from notes, (net)	$ 1,280,939	$ 2,250,000
Payment of notes	—	(250,000)
Net (purchases) and sales of common stock	—	(165)
Net cash provided by financing activities	$ 1,280,939	$ 1,999,835
Net change in cash and cash equivalents:	2,532,191	(865,828)
Cash and cash equivalents - beginning of year	1,624,242	2,490,070
Cash and cash equivalents - end of year	$ 4,156,433	$ 1,624,242
Supplemental cash flow disclosures:		
Income taxes paid	$ 726	$ 5,020
Interest paid	$ —	$ 25,000

The accompanying footnotes are an integral part of these consolidated financial statements

NOTE 1 – ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Decoy Therapeutics, Inc. (the "Company") is a development stage biopharmaceutical company with a mission to revolutionize the design, development, and commercialization of peptide-conjugate therapeutics. The Company believes that its evolving, proprietary ***I***mmediate ***P***eptide/***P***PMO/***P***NA ***A***lpha-helical ***C***onjugate ***T***echnology (IMP^{3}ACT) platform represents a fundamental revolution in peptide-conjugate drug discovery by substantially accelerating the time to design and validate new lead quality drug candidates from years to months or even weeks. The Company's IMP^{3}ACT platform tames the complexity of the peptide-conjugate modality by using machine learning (ML) and artificial intelligence (AI), coupled with world-leading high-speed synthesis of peptide-conjugates and a strong understanding of target biology, to rapidly interrogate and reengineer naturally existing peptides that bind to disease mediating targets.

The Company employs a multi-parameter approach to design and optimization, simultaneously focusing on a broad set of characteristics that will be important through the development and commercialization of the drug, such as chemical affinity, agonist/antagonist activity, enzymatic resistance for enhanced pharmacokinetics, formulation, and manufacturing. The Company believes its approach will significantly decrease timelines, risk, and expense downstream in the therapeutic development process, and can still be executed quickly by the IMP^{3}ACT platform during the design and lead optimization phase.

The Company plans to deploy the IMP^{3}ACT platform in two major target areas: (a) antiviral fusion inhibitors and (b) G-Protein Coupled Receptors (GPCRs). In both target areas there is strong evidence that single peptide-conjugates can be designed to affect multiple disease states, creating the potential for multi-indication therapeutics with broad activity from a single drug. The Company believes both target areas also offer substantial commercial opportunities to address significant unmet medical needs.

The Company was incorporated in Delaware on April 17, 2020 and has a principal place of business in Cambridge, Massachusetts. The Company has a wholly-owned Canadian subsidiary, Decoy Drug Discovery Canada, which was incorporated on July 8, 2021. The Company's Canadian subsidiary's primary activities have been related to sponsored research activities at the University of Toronto and The University of Waterloo.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early stage life science companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the industry, including rapid technological change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals.

Going Concern Evaluation:

As of December 31, 2023, the Company's primary source of liquidity is its cash and cash equivalent balances. Until the Company is successful in gaining regulatory approvals, it is unable to sell the Company's product in any market. Without revenues, the Company is reliant on funding obtained from investment in the Company to maintain business operations until the Company can generate positive cash flows from operations. The Company cannot predict the extent of future operating losses and accumulated deficit, and it may never generate sufficient revenues to achieve or sustain profitability.

The Company has generated an accumulated deficit of $15.1 million since its inception and will require substantial additional capital to fund its research and development and ongoing operating expenses. It is subject to risks common to companies in the biotechnology industry, including, but not limited to, development by the Company or its competitors of technological innovations, risks of failure of clinical studies, dependence on key personnel, protection of proprietary technology and compliance with government regulations. If access to capital is not achieved in the near term, it will materially harm the Company's business, financial condition and results of

operations to the extent that the Company may be required to cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

NOTE 2 - LIQUIDITY RISKS AND OTHER UNCERTAINTIES

The Company has incurred net losses every year since inception and has an accumulated deficit of approximately $15.1 million at December 31, 2023. The Company has historically funded its operations through debt and equity financings. At December 31, 2023, the Company had cash balances totaling $4.2 million.

The Company will need to arrange additional financing in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company is looking to raise additional funds through any combination of additional equity and debt financings or from other sources, however, the Company has no guaranteed source of capital that will sustain operations for a period of one year from the date these financial statements are available to be issued. There can be no assurance that any such potential financing opportunities will be available on acceptable terms, if at all.

Other risks and uncertainties:

The Company is subject to risks common to development stage biopharmaceutical companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, pre-clinical and clinical trial outcome risks, regulatory approval risks, uncertainty of market acceptance and additional financing requirements.

The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products.

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation:

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), which have been consistently applied, reflecting the operations of Decoy Therapeutics Inc. since inception. All intercompany accounts and transactions have been eliminated in consolidation.

Principles of Consolidation:

The accompanying consolidated financial statements include the accounts of Decoy Therapeutics, Inc. and its wholly owned subsidiary. All intercompany transactions and balances are eliminated in consolidation. The functional currency of Decoy Drug Discovery Canada, Inc., a wholly-owned subsidiary of the Company, is the U.S. dollar. Consolidated balance sheet accounts of the Company's subsidiary are remeasured into U.S. dollars using the exchange rate in effect at the consolidated balance sheet date while expenses are remeasured using the average exchange rate in effect during the period. Gains and losses arising from remeasurement of the wholly owned subsidiary's financial statements are included in the determination of net loss.

Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience

and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and cash equivalents:

The Company considers all highly liquid investments and short-term debt instruments with original maturities of three months or less to be cash equivalents. From time to time during the periods presented, the Company has had bank account balances in excess of federally insured limits where substantially all cash is held in the United States. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Fair value of financial instruments:

The Company considers its cash and cash equivalents, accounts payable, accrued expenses to meet the definition of financial instruments. The carrying amounts of these financial instruments approximated their fair values due to the short maturities.

The Company measures fair value as required by ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (see Note 5).

Property and equipment:

Property and equipment are recorded at cost and are depreciated when placed in service using the straight-line method based on their estimated useful lives as follows:

	Estimated Useful Life
Laboratory equipment	5 years
Computer equipment and software	3 years
Office furniture and equipment	5 years

For the years ended December 31, 2023 and 2022, the Company's had property and equipment depreciation expense of $43,977 and $17,340, respectfully.

Impairment of long-lived assets:

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded during the years ended December 31, 2023 and 2022.

Warrants:

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net- share settlement), provided that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (a) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control) or (b) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The Company assesses classification of its warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company evaluated its issued and outstanding warrants to assess their proper classification using the applicable criteria enumerated under U.S. GAAP and determined that such warrants meet the criteria for liability classification in the accompanying consolidated balance sheets as of December 31, 2023 and December 31, 2022, respectively.

Grant income:

The Company has received grants from two funding sources, including a private not-for-profit organization and a federal agency. Grant income consists of income earned from grants to conduct development research. Funds received in advance of services being performed are recorded as deferred income. Income under the not-for-profit and federal agency grants is recognized as labor and material costs are incurred. Labor costs are recognized based on actual salary costs incurred related to the projects, and material costs are recognized based on actual expenditures. As of December 31, 2023 and December 31, 2022, the Company has recognized a total of $0.67 million and $0.74 million of income related to these grants, and has received a total of $1.1 million and $424,000 in cash receipts.

Research and development:

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues costs incurred by external service providers, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

Key Relationships & Licenses:

In June 2020, the Company entered into a one-year, non-exclusive licensing agreement with the Massachusetts Institute of Technology (“MIT”) related to developing potential treatments for Covid-19 using a variety available resources, services and technologies from MIT. Additionally, in July 2020, the Company entered into a Sponsored Research Agreement and option agreement with Columbia University to evaluate a molecule to block the transmission of Covid-19, Neither collaboration remains active.

The Company has attracted non-dilutive investments from the European Union’s IMI-CARE Consortium, The Bill & Melinda Gates Foundation (“BMGF”), The U.S. Government’s Biological Research and Development Authority (“BARDA”) and Johnson & Johnson through the U.S. Government’s Blue Knight Blue Knight Program.

Income taxes:

The Company accounts for its income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company maintains a full valuation allowance on its existing deferred tax assets.

The Company also accounts for uncertain tax positions using the more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company’s income tax returns. As of December 31, 2023 and 2022, the Company had no uncertain tax positions which affected its financial position and its results of operations or its cash flows. The Company will continue to evaluate for uncertain tax positions in the future. If at any time the Company should record interest and penalties in connection with income taxes, the interest and the penalties will be expensed within the interest and general and administrative expenses, respectively.

Stock based compensation:

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The Company utilizes the simplified method to estimate the expected term. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield was assumed to be zero as the Company has not paid and dividends since its inception and does not anticipate paying dividends in the foreseeable future.

Earnings (loss) per share:

The Company reports loss per share in accordance with ASC 260-10, *Earnings Per Share*, which provides for calculation of "basic" and "diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing net income or loss available to shareholders by the weighted average shares outstanding for the period. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. The calculation of diluted net earnings (loss) per share gives effect to ordinary shares equivalents; however, potential shares are excluded if their effect is anti-dilutive.

For the year ended December 31, 2023, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 232,092 shares, 886,439 shares from the conversion of outstanding convertible notes and outstanding stock options to purchase 469,350. For the year ended December 31, 2022, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 232,092 shares, 783,776 in shares from the conversion of outstanding convertible notes and outstanding stock options to purchase 237,850. The inclusion of these warrants, shares from convertible notes and stock options for both 2023 and 2022 in the denominator would be anti-dilutive.

NOTE 4 – NOTES

Unsecured Promissory Note

In October 20, 2021, the Company issued an unsecured promissory note (the "2021 Promissory Note") in exchange for cash proceeds of $250,000. The term of the 2021 Promissory Note is nine months unless earlier settled upon an automatic payment condition, as further described below. The specific terms and conditions are as follows:

1. **Interest**: Interest of $25,000 shall accrue on the outstanding principal amount for the first 90 days of the loan and thereafter interest shall accrue on $275,000 at a rate per annum equal to 5% compounded each month thereafter until paid.

2. **Automatic Payment:** If at any time during the term of the 2021 Promissory Note the Company had issued and sold $650,000 or more in additional capital exclusive of the 2021 Promissory Note and via the sale of the Company's common stock, $0.001 par value per share (the "Common Stock") or any securities convertible into Common Stock (such event being an "Automatic Payment Date"), then the Company would be required to pay the holder the entire outstanding principal amount within fifteen days after the closing of the relevant transactions. If the Automatic Payment Date occurred before 90 days from the date of the 2021 Promissory Note, then interest of $25,000 would immediately accrue on the outstanding principal amount on the Automatic Payment Date. No such Automatic Payment Date occurred during the term of the 2021 Promissory Note.

3. **Issuance of Company Equity Securities:** Within 90 days from the date of the Promissory Note, the Company issued 3,930 shares of Common Stock to the holder at a price of $0.013 (representing current fair

market value based on the Company's most recent 409A valuation at that time) as additional consideration for extending the loan evidenced by the 2021 Promissory Note.

On January 5, 2022, the Company repaid the 2021 Promissory Note in full, including the $25,000 interest specified above. The 2021 Promissory Note was considered settled at that time.

Accounting Guidance

The 2021 Promissory Note is considered an obligation (or liability) of the Company as prescribed by Accounting Standards Codification ("ASC") 470-10. The Company has elected the fair value option under ASC 825 and ASC 825-10-15-4(a) for the 2021 Promissory Note and will measure the 2021 Promissory Note, as a whole, at fair value, with changes in fair value reported in earnings. As neither ASC 815 nor ASC 825 prescribes the location in which the Company should report fair value changes in the income statement, the Company will elect a policy to present all changes in fair value of the 2021 Promissory Note as a component of interest expense.

The embedded forward found in the 2021 Promissory Note requiring the Company to issue 3,930 shares of its Common Stock does not represent an embedded derivative. Since the contract itself does not permit/require net settlement, the contract cannot be traded on active markets, and the shares underlying the forward are not readily convertible to cash, a separate instrument with the same terms as the embedded forward would not meet the definition of a derivative. This means that the embedded forward does not meet the condition in ASC 815-15-25-1(c) and does not need to be bifurcated from the 2021 Promissory Note. Upon issuance of the shares underlying the forward, the Company will record the cash proceeds received, Common Stock (at par), and additional paid in capital.

SEED Tranche A Convertible Promissory Note

On November 4, 2020, the Company entered into a Convertible Promissory Note ("Tranche A Note") in exchange for $250,000 cash proceeds. The Tranche A Note bears interest at 5% per annum computed on a 356-day year. The stated maturity date of the Tranche A Note is December 31, 2021, though this was subsequently amended on February 28, 2022 to extend the maturity date through April 12, 2023, and again amended on November 13, 2023 to extend the maturity date through June 30, 2024.

The Tranche A Note contains a variety of variable share settlement provisions, as indicated below:

Elective Conversion. In the event that the Company issues and sells shares of its equity securities to investors (a "Subsequent Financing"), then the holder of the Tranche A Note shall have the rights and option to convert the outstanding principal amount of the Tranche A Note and any unpaid accrued interest in whole into the equity securities sold in the Subsequent Financing at a conversion price equal to the lowest of the following: (i) the cash price paid per share for equity securities by the investors in the Subsequent Financing; (ii) $0.8333334 per share (equitably adjusted to account for stock splits, stock dividends and similar events with respect to the Common Stock between the date of the Tranche A Note and the date of such conversion); and (iii) the lowest exercise or conversion price per share of Common Stock underlying any stock option, stock appreciation right, or other stock-based equity award under the Company's stock-based awards (the "Stock Plan"). The issuance of equity securities pursuant to the conversion of this Tranche A Note shall otherwise be upon and subject to the same terms and conditions applicable to equity securities sold in the Subsequent Financing.

Automatic Conversion upon a Qualified Financing. In the event that the Company issues and sells shares of its equity securities to investors while the Tranche A Note remains outstanding in an equity financing with total proceeds to the Company of not less than $5,000,000, excluding the conversion of the Tranche A Note or other convertible securities issued for capital raising purposes (a "Qualified Financing"), then the outstanding principal amount of the Tranche A Note and any unpaid accrued interest shall automatically convert in whole without any further action by the holder into equity securities sold in the Qualified Financing at a conversion price equal to the lowest of the following: (i) the cash price paid per share for equity securities by the investors in the Qualified Financing; (ii) $0.8333334 per share (equitably adjusted to account for stock splits, stock dividends and similar events with respect to the Company's Common Stock between the date of the Tranche A Note and the date of such conversion); and (iii) the lowest exercise or conversion price per share of Common Stock underlying any stock

option, stock appreciation right, or other stock-based equity award under the Company's Stock Plan, in each case granted to any of the current four stockholders of the Company between the date of the Tranche A Note and the date of such conversion (as equitably adjusted as provided in clause (ii) above). The issuance of equity securities pursuant to the conversion of this Tranche A Note shall otherwise be upon and subject to the same terms and conditions applicable to equity securities sold in the Qualified Financing.

Change of Control. If the Company consummates a change of control (as further defined below) while the Tranche A Note remains outstanding, the Company shall repay the holder in cash in an amount equal to the outstanding principal amount of this Tranche A Note plus any unpaid accrued interest on the original principal; provided, however, that upon the written election of the holder made not less than five days prior to such change of control, the Company shall convert the outstanding principal balance of this Tranche A Note and any unpaid accrued interest into shares of Common Stock at a conversion price equal to the lower of the following: (i) $0.8333334 per share (equitably adjusted to account for stock splits, stock dividends and similar events with respect to the Common Stock between the date hereof and the date of such conversion); and (ii) the lowest exercise or conversion price per share of Common Stock underlying any stock option, stock appreciation right, or other stock-based equity award under the Company's Stock Plan, in each case granted to any of the current four stockholders of the Company between the date hereof and the date of such conversion (as equitably adjusted as provided in clause (i) above). For purposes of the Tranche A Note, a change of control means (i) a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the shares of capital stock of the Company immediately prior to such consolidation, merger or reorganization continue to represent a majority of the voting power of the surviving entity immediately after such consolidation, merger or reorganization; (ii) any transaction or series of related transactions to which the Company is a party in which in excess of 50% of the Company's voting power is transferred; or (iii) the sale or transfer of all or substantially all of the Company's assets, or the exclusive license of all or substantially all of the Company's material intellectual property; provided that a change of control shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor, indebtedness of the Company is cancelled or converted or a combination thereof.

Neither party has the ability to redeem the Tranche A Note prior to the stated maturity date and there are no other provisions requiring accounting analysis.

The Tranche A Note is considered an obligation (or liability) of the Company as prescribed by ASC 470-10 and/or 480-10-25-14(a).). The Company has elected the fair value option under ASC 825-10-15-4(a) and paragraphs 4-5 of ASC 815-15-25 for each Tranche A Note and will instead measure each Tranche A Note, as a whole, at fair value, with changes in fair value reported in earnings. The Company will present all changes in fair value of the Tranche A Note as a component of interest expense. For the years ended December 31, 2023 and 2022, the Company recorded approximately $13,000 and $13,000 respectively, of accrued interest related to the Tranche A Note. For the years ended December 31, 2023 and 2022, the Company recorded income (expense) approximately of ($2,741,000) and ($278,000), respectively, as a change in the fair value of debt in the statement of operations.

SEED Convertible Promissory Notes

On March 25, 2021, April 12, 2021, and April 5, 2022, the Company entered into three separate Convertible Promissory Notes (the "Seed Notes") in exchange for $650,000 total cash proceeds. The Seed Notes bear interest at 8% per annum computed on a 365-day year. The stated maturity date of each Seed Note is two years (24 months) after the Issuance Date. The maturity date of the April 5, 2022 Seed Note has been extended to December 31, 2024. The maturity dates of the March 25, 2021 and April 12, 2021 Seed Notes have been extended to June 30, 2024. At the time of issuance of these financials, the Company is in process of further extending the maturity dates for the March 25, 2021 and April 12, 2021 Seed Notes. The Seed Notes are considered an obligation (or liability) of the Company as prescribed by ASC 470-10 and/or 480-10-25-14(a). The Company has elected the fair value option under ASC 825-10-15-4(a) and paragraphs 4-5 of ASC 815-15-25 for each Seed Note and will instead measure each Seed Note, as a whole, at fair value, with changes in fair value reported in earnings. The Seed Notes are convertible at the option of the Holder subject to the following conditions which are identical across the three Seed Notes:

Conversion upon a Qualified Financing. In the event that the Company issues and sells shares of its equity securities to investors while the Seed Notes remain outstanding in an equity financing with total proceeds to the Company of not less than $5,000,000 (excluding the conversion of the Seed Notes or other convertible securities issued for capital raising purposes (a "Seed Note Qualified Financing"), then the outstanding principal amount of the Seed Notes and any unpaid accrued interest shall automatically convert in whole without any further action by the holders into equity securities sold in the Seed Note Qualified Financing at a conversion price equal to the lesser of (i) the cash price paid per share for equity securities by the investors in the Seed Notes Qualified Financing multiplied by 0.80, and (ii) the quotient resulting from dividing $20,000,000 by the number of outstanding shares of Common Stock of the Company immediately prior to the Seed Note Qualified Financing (assuming conversion of all securities convertible into Common Stock and exercise of all outstanding options and warrants, but excluding the shares of equity securities of the Company issuable upon the conversion of Seed Notes or other convertible securities issued for capital raising purposes. The issuance of equity securities pursuant to the conversion of the Seed Notes shall be upon and subject to the same terms and conditions applicable to equity securities sold in the Seed Note Qualified Financing. If the conversion price of the Seed Notes is less than the price per share at which equity securities are issued in the Seed Note Qualified Financing, the Company may, solely at its option, elect to convert the Seed Notes into shares of a newly created series of preferred stock having the identical rights, privileges, preferences and restrictions as the equity securities issued in the Seed Note Qualified Financing, and otherwise on the same terms and conditions, other than with respect to: (i) the per share liquidation preference and the conversion price for purposes of price-based anti-dilution protection, which will equal the conversion price; and (ii) the per share dividend, which will be the same percentage of the conversion price as applied to determine the per share dividends of the investors in the Seed Note Qualified Financing relative to the purchase price paid by the investors.

Optional Conversion at non-Qualified Financing. In the event the Company consummates, while this Seed Notes remain outstanding, an equity financing pursuant to which the Company sells shares of preferred stock in a transaction that does not constitute a Seed Note Qualified Financing, then the Seed Note holders shall have the option to treat such equity financing as a Seed Note Qualified Financing on the same terms set forth herein.

Maturity Date Conversion. In the event that the Seed Notes remain outstanding on the maturity sate, then the outstanding principal balance of the Seed Notes and any unpaid accrued interest shall automatically without any further action by the holders convert as of the maturity date into shares of Common Stock at a conversion price equal to the quotient resulting from dividing $20,000,000 by the number of outstanding shares of Common Stock as of the maturity date assuming conversion of all securities convertible into Common Stock and exercise of all outstanding options and warrants, but excluding the shares of equity securities of the Company issuable upon the conversion of the Seed Notes or other convertible securities issued for capital raising purposes.

Change of Control. If the Company consummates a change of control (as further defined below) while the Seed Notes remain outstanding, the Company shall repay the holders in cash in an amount equal to the outstanding principal amount of the Seed Notes plus any unpaid accrued interest on the original principal; provided, however, that upon the written election of the holders made not less than five days prior to the change of control, the Company shall convert the outstanding principal balance of the Seed Notes and any unpaid accrued interest into shares of Common Stock at a conversion price equal to the quotient resulting from dividing $20,000,000 by the number of outstanding shares of Common Stock of the Company immediately prior to the change of control. For purposes of the Seed Notes, a change of control means (i) a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the shares of capital stock of the Company immediately prior to such consolidation, merger or reorganization continue to represent a majority of the voting power of the surviving entity immediately after such consolidation, merger or reorganization; (ii) any transaction or series of related transactions to which the Company is a party in which in excess of 50% of the Company's voting power is transferred; or (iii) the sale or transfer of all or substantially all of the Company's assets, or the exclusive license of all or substantially all of the Company's material intellectual property.

The Seed Notes contain as side letter that contains participation and put rights. Aside from the conditions noted in the side letter, neither party has the ability to redeem the loan prior to the stated maturity date and there are no other provisions requiring accounting analysis.

For the year ended December 31, 2023 and 2022 the Company recorded approximately $52,000 and $46,000 of accrued interest. For the year ended December 31, 2023 and 2022 the Company recorded income (expense) related to the Seed Notes of approximately of ($324,000) and ($98,000), respectively as a change in the fair value of debt in the Statement of Operations.

Senior Secured Convertible Promissory Notes

On December 22, 2021, and December 23, 2021, the Company entered into two separate Senior Secured Convertible Promissory Notes (the "Senior Notes") in exchange for up to a combined $4M total cash proceeds. The stated maturity date for each Senior Note is March 22, 2023, and March 23, 2023, respectively. Per an amendment dated March 22, 2023, the Company elected to extend the maturity date for an additional six months for both Senior Notes. The Company subsequently extended the maturity date for both Senior Notes to June 30, 2024. At the time of issuance of these financials, the Company is working on an updated extension to these Senior Notes. The Senior Notes are considered an obligation (or liability) of the Company as prescribed by ASC 470-10 and/or 480-10-25-14(a). The Company has elected the fair value option under ASC 825-10-15-4(a) and paragraphs 4-5 of ASC 815-15-25 for each Senior Note and will instead measure each Senior Note, as a whole, at fair value, with changes in fair value reported in earnings.

The Senior Notes contain an option to extend the maturity date by an additional six months for an extension premium of 110% which is exercisable by the issuer. The Senior Notes bear interest at 12% per annum computed on a 360-day year and contain the following conversion and redemption features:

At any time after the issuance sate of the Senior Notes, the Senior Notes shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock. The number of shares of Common Stock issuable upon conversion of any conversion amount, including all accrued and unpaid interest with respect to such portion of the principal amount, divided by the conversion amount. The conversion amount attributable to the first disbursement conversion price (initially $10.47). If a subsequent disbursement is made in a six month period following the issuance date, initially 110% of the first disbursement conversion price, or if a subsequent disbursement is made after the six month period following the issuance date but prior to the date that is one year from the issuance date, initially 125% of the first disbursement conversion price. From and after a date upon which the Company becomes a publicly traded entity (as defined in the Senior Note), the Company shall not implement the conversion of any portion of the Senior Notes, and the holders shall not have the right to convert any portion of the Senior Notes.

The Company issued the Senior Notes together with detachable warrants (the "Warrants") to purchase shares of the Company's Common Stock pursuant to a warrant purchase agreement. The Warrants were issued after each scheduled disbursement. The Company believes that the Warrants issued in connection with the Senior Notes are liability- classified under ASC 480-10-25-8, because the Company could be required to repurchase the Warrants under the terms thereof for reasons outside the control of the Company, including in the event of default (as defined in the Warrants). Even if the Warrants were not liability-classified under ASC 480, they would be classified as liabilities under ASC 815 because the Warrants meet the definition of a derivative under ASC 815-10-15-8. Because the Warrants are liability-classified, they will be initially and subsequently measured at fair value until settlement or expiry, with changes in fair value reported in the Statement of Income. The Company will also be measuring the related Senior Notes issued in conjunction with the Warrants at fair value. To the extent that the proceeds received from investors are less than the combined fair values of the Senior Notes and Warrants, the difference will be reported as an immediately loss in the statement of operations. For the years ended December 31, 2023 and 2022 the Company recorded income (expense) approximately of $251,000 and ($108,000) as a change in the fair value of warrant in the Statement of Operations.

Finally, in connection with the issuance of the Senior Notes, the Company also entered into a Registration Rights Agreement (the "RRA") that outlines the actions the Company will take to register the securities underlying the Senior Notes and Warrants with the U.S, Securities and Exchange Commission. If the Company does not comply with the registration requirements under the RRA, the holders are entitled to receive payments if the Company is unable to comply with the promises in the RRA. The Company shall pay to each holder an amount in cash, as partial liquidated damages and not as a penalty, equal to 1% of the purchase price paid by such holder pursuant to the purchase agreement for the Senior Notes. The Company analyzed ASC 825-20-25-1 for the accounting treatment for

registration agreements related to financing arrangements. The Company determined the existence of the registration payment arrangement does not affect the accounting for the Senior Notes and the registration payment arrangement should not be recognized at this time under ASC Subtopic 450-20. ASC 450-20-25-1, requires contingent obligations to be recorded when a loss is probable of occurrence and reasonably estimable. As of December 31, 2023, it is not probable that the Company will be subject to penalties related to the RRA. The Company will reassess this conclusion each reporting period.

For the year ended December 31, 2023 and 2022 the Company recorded approximately $480,000 and $307,000 of accrued interest related to the SSCPN. For the year ended December 31, 2023 and 2022 the Company recorded income (expense) approximately of $2,578,000 and $327,000 as a change in the fair value of debt in the Statement of Operations. At origination the Company incurred $45,000 of dept issuance cost related to these SSCPN, during the years ended December 31, 2023 and 2022 the company amortized $22,000 and $22,500 of these costs.

Bridge Notes

During the year ended December 31, 2023, the Company entered into a series of Promissory Notes (“Bridge Notes”) in exchange for notional proceeds totaling $1,448,899. The terms and conditions of each Bridge Note are identical except for the proceeds invested by each investor and the maturity date of each Bridge Note. The stated maturity date for these Bridge Notes is twelve months from the date of issuance. At the time of issuance of these financials, the Company is working on an updated extensions to these Bridge Notes.

Each of the Bridge Notes was issued at an original issue discount with principal and accrued interest due and payable on the earlier of one year from issuance date, or the date of the closing of an initial public offering of the Company (“IPO”). The Company also has the option to repay the loan before the stated maturity date without penalty. The securities purchase agreement pursuant to which the Bridge Notes were sold requires that, in addition to repayment of principal and interest, shares of the Company’s Common Stock be issued to the holder according to the following conditions: 100% of the principal value of the note divided by (A) the Company’s IPO price or (B) if the Company fails to complete an IPO before maturity, the number of shares calculated using a $40 million pre-money valuation for the Company and the number of the Company’s shares outstanding at maturity.

Interest shall accrue to the holders on the aggregate then outstanding principal amount of the Bridge Notes at the rate of 10% per annum, calculated on the basis of a 360-day year and shall accrue daily commencing on the original issue date of the Bridge Notes until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts which may become due hereunder, has been made.

The Bridge Notes are obligations of the Company that could be settled in cash (traditional debt under ASC 470) and a variable number of shares as per ASC 480-10-25-14(a). Under either ASC Topic, pursuant to U.S. GAAP the Bridge Notes would be presented the balance sheet as a liability at amortized cost.

The Bridge Notes contain a number of embedded features that should be evaluated for bifurcation. The Company will elect the fair value option to account for each of the Bridge Notes, as permitted by ASC 825-10-15 and ASC 815-15-25.

Based on the Company’s analysis, all three conditions under ASC 815-15-25-1 are met and the embedded share settlement feature would ordinarily require bifurcation as an embedded derivative. Based on the conditions in ASC 825-10-15 and ASC 815-15-25, the Company elected to apply the fair value option for each of the Bridge Notes and will not be required to bifurcate any embedded features. Neither ASC 825 nor ASC 815 prescribes the location in which the Company should report fair value changes in the income statement, the Company will elect a policy to present all changes in fair value of the Bridge Notes as a component of interest expense in the Statement of Income.

For the year ended December 31, 2023 the Company recorded approximately $21,000 of accrued interest related to these Bridge Notes. At origination during the year ended December 31, 2023 the Company incurred $145,000 of dept issuance cost related to these Bridge Notes, during the year ended December 31, 2023 the company amortized $30,556 of these costs.

Demand Notes

On June 13, 2023, the Company issued three separate notes ("Demand Notes") in exchange for gross cash proceeds totaling $150,000, prior to the payment of offering costs. The terms and conditions of each Demand Note are identical. Each Demand Note was issued at a discount and must be repaid upon the earlier of the maturity date or within 5 days of the demand by the holder. The specific terms of the Demand Notes are as follows:

In exchange for receipt of Demand Notes, the Company promises to pay the holders, the principal sum of $166,665 together with interest thereon from the date hereof, at 10% per annum, with interest and principal being immediately payable on the earlier of (i) the maturity date and (ii) five days from the date that the Holder demands repayment. The maturity date shall be 90 days from the issuance date of each Demand Note. At maturity on August 12, 2023 two of these three Demand Notes were repaid in full, the one remaining note is outstanding to an employee/founder of the Company – See related party (Note 9)

The Demand Notes are obligations of the Company that will be settled in cash and therefore represent traditional debt. Traditional debt is accounted for under ASC 470 and requires presentation on the balance sheet as a liability at amortized cost.

The Demand Notes contain an embedded written put right. Specifically, the investors of each Demand Note have the right to demand repayment with five days' notice. The Demand Notes were evaluated to determine whether the embedded features should be bifurcated, or detached from the note and accounted for separately if it meets the criteria in ASC 815-15-25-1. As neither ASC 825 nor ASC 815 prescribes the location in which the Company should report fair value changes in the income statement, the Company elected a policy to present all changes in fair value of the Demand Notes as a component of interest expense in the Statement of Operations. For the years ended December 31, 2023 the Company recorded approximately $3,000 of accrued interest related to these Demand Notes.

Below is a schedule of note balances as of the years ended December 31, 2023 and 2022:

	Promissory Notes	Seed Tranche A	Seed	Senior Secured Convertible Note
Beginning Balance December 31, 2021	$ —	$ 400,000	$ 250,000	$ 2,000,000
Change in principal balance	—	250,000	—	2,000,000
Beginning Balance December 31, 2022	$ —	$ 650,000	$ 250,000	$ 4,000,000
Change in principal balance	1,544,444	—	—	—
Ending Balance December 31, 2023	$ 1,544,444	$ 650,000	$ 250,000	$ 4,000,000

NOTE 5 - FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company applies fair value accounting for all assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities the Company considers the principal or most advantageous market in which it would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. For certain instruments, including cash and cash equivalents, accounts payable, and accrued expenses, it was estimated that the carrying amount approximated fair value because of the short maturities of these instruments.

Fair value is estimated using various valuation models, which utilize certain inputs and assumptions that market participants would use in pricing the asset or liability. The inputs and assumptions used in valuation models are classified in the fair value hierarchy as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Quoted market prices for similar instruments in an active market; quoted prices for identical or similar assets and liabilities in markets that are not active; and model-derived valuations inputs of which are observable and can be corroborated by market data.

Level 3: Unobservable inputs and assumptions that are supported by little or no market activity and that are significant to the fair value of the asset and liability. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining the appropriate hierarchy levels, the Company analyzes the assets and liabilities that are subject to fair value disclosure. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to their fair value measurement.

The following table presents the Company's liabilities that are measured at fair value on a recurring basis by fair value hierarchy at December 31, 2023 and 2022:

December 31, 2023	Level 1	Level 2	Level 3	Total
Promissory note	—	—	$ 1,425,939	$ 1,425,939
Seed Tranche A	—	—	4,122,000	4,122,000
Seed	—	—	1,073,000	1,073,000
Senior Secured Convertible Note	—	—	6,523,556	6,523,556
SSCPN Warrant	—	—	131,000	131,000
Total	$ —	$ —	$ 13,275,495	$ 13,275,495

December 31, 2022	Level 1	Level 2	Level 3	Total
Seed Tranche A	$ —	$ —	$ 1,381,000	$ 1,381,000
Seed	—	—	749,000	749,000
Senior Secured Convertible Note	—	—	4,038,000	4,038,000
SSCPN Warrant	—	—	382,000	382,000
Total	$ —	$ —	$ 6,550,000	$ 6,550,000

The following shows the movement of the warrant and note liability balances during the years ended December 31, 2023 and 2022.

The following shows the movement of the warrant liability balance during 2021 and the year ended December 31

	SSCPN Warrants	Seed Tranche A	Seed	Senior Secured Convertible Note
Beginning Balance December 31, 2021	$ 274,000	$ 1,103,000	$ 401,000	$ 1,733,000
Change in principal balance	—	—	—	2,000,000
Change in Fair value	108,000	278,000	348,000	305,000
Beginning Balance December 31, 2022	$ 382,000	$ 1,381,000	$ 749,000	$ 4,038,000
Change in Fair value	(251,000)	2,741,000	324,000	2,485,556
Ending Balance December 31, 2023	$ 131,000	$ 4,122,000	$ 1,073,000	$ 6,523,556

Warrants issued to the Senior Note holders (Note 4) were classified as a liability on issuance.

NOTE 6 – STOCK BASED COMPENSATION

In May 2020, the Company adopted the Decoy Equity Incentive Plan (the "Plan"), pursuant to which the Company may grant incentive stock options ("ISOs"), non-qualified stock options, restricted stock, and stock grants to purchase up to 1,800,000 shares of Common Stock. In December 2023, the Company amended the Plan to increase the number of shares available under the Plan to 2,250,000 shares of Common Stock. Under the Plan, ISOs may not be granted with an exercise price less than fair value of the Company's Common Stock on the date of the grant, and all options generally vest over a four-year period. These options expire ten years after the grant date.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the Plan. Options granted by the Company typically vest over a four year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options are exercisable from the date of grant for a period of ten years. For options granted to date, the exercise price equaled the estimated fair value of the Common Stock as determined by the board of directors on the date of grant.

The following table summarizes stock-based activities under the Amended Plan:

	Options	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2021	64,500	$ 0.01	9.16
Granted	174,600	0.72	
Forfeited/Cancelled	(1,250)	0.01	
Outstanding at December 31, 2022	237,850	$ 0.53	9.08
Granted	231,500	3.56	
Forfeited/Cancelled	—	—	
Outstanding at December 31, 2023	**469,350**	**$ 2.03**	**8.96**
Exercisable options at December 31, 2023	209,094	$ 0.50	8.05

The intrinsic value of outstanding options at December 31, 2023 was approximately $704,000.

Stock options granted during the year ended December 31, 2023, were valued using the Black-Scholes option-pricing model with the following weighted average assumptions:

	December 31, 2023	December 31, 2022
Expected volatility	97.9 %	103.1 %
Risk-free interest rate	3.9 %	3.0 %
Expected dividend yield	0.0 %	0.0 %
Expected life of options in years	5.5	5.5
Exercise Price	$ 3.56	$ 0.72
Fair value of common stock	$ 2.61	$ 0.01
Estimate fair value of option	$ —	$ —

Stock based compensation expense was $70,486 ($45,767 included in research and development expense and $24,719 included in general and administrative expenses) in the year ended December 31, 2023. Stock based compensation expense was $320 ($203 included in research and development expense and $117 included in general and administrative expenses) in the year ended December 31, 2022.

At December 31, 2023, the total unrecognized compensation expense related to non-vested options was approximately $534,000 and is expected to be recognized over the remaining weighted average service period of approximately 1.9 years.

NOTE 7 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are as follows:

	December 31, 2023	December 31, 2022
Prepaid R&D costs	$ 95,360	$ 17,001
Prepaid rent	16,023	15,436
Prepaid software subscriptions	49,828	22,267
Prepaid professional fees	20,000	—
Prepaid other	13,453	11,160
Total	**$ 194,664**	**$ 65,864**

NOTE 8 – ACCRUED EXPENSES

Accrued expenses are as follows:

	December 31, 2023	December 31, 2022
Payroll	$ 72,039	$ 50,143
Professional fees	103,071	—
Other expenses	9,914	9,358
Total	**$ 185,024**	**$ 59,501**

NOTE 9 – RELATED PARTY TRANSACTIONS

Due to Officers/Founders:

As of December 31, 2023, one officer/founder of the Company had an outstanding Demand Note (See Note 4) in the principal amount of $55,555, plus accrued interest of $2,968. This note accrues interest at 10% and has a maturity date of December 28, 2024.

NOTE 10 – LICENSE AGREEMENTS AND GRANTS

The Company has received significant grants are from The Bill and Melinda Gates Foundation, Johnson & Johnson through the U.S. government's Blue Knight Program, the European Union's IMI.CARE.EU Consortium, the Canadian government's National Research Council, and GOOGLE's AI Startup Program.

Key Relationships, Licenses and Grants

The Company received a foundation grant from the Bill and Melinda Foundation for the development of a nasally inhaled, low cost, peptide conjugate *pan-Coronavirus* antiviral inhibitor. The initial award in September 6, 2021 provided up to a total of approximately $904,000 and expired on February 28, 2023. The Company initially recorded the proceeds in Deferred income. As work was commenced under the grant the company recognizes income from deferred income.

In 2023 the Company entered into a supplemental grant with the Bill and Melinda Foundation for an additional $4,084,500 for continued work on the nasally inhaled, low cost, peptide conjugate *pan-Coronavirus* antiviral inhibitor reference above. The Company received payment of $3,500,000 in September 28, 2023, the remaining $584,500 will be received after the completion of certain milestones .

The Company recognized income of approximately $235,000 and $739,000 in the years ended December 31, 2023 and 2022, respectively. The Company had approximately $3,408,000 and $144,000 in deferred income balances related to this grant for the years ended December 31, 2023 and 2022, respectably.

Johnson and Johnson Quickfire Grants

The Company received a grant from the Johnson and Johnson through the U.S. government's Blue Knight Program (Quickfire Grant) for experiments relating to the pharmacokinetics and tolerability of the aforementioned *pan-Coronavirus* inhibitor in the Human Airway Epithelium (HAE) model. The initial award to the Company in January 31, 2023 provided for $100,000. The Company initially recorded the proceeds in deferred income. As work was commenced under the grant the company recognizes income from deferred income.

In September 22, 2023 the Company received the first $500,000 of an additional Quickfire grant for $1,000,000 for work to investigate the potential for broader therapeutic use of the aforementioned *pan-Coronavirus* inhibitor. The Company initially recorded the proceeds in deferred revenue. As work was commenced under the grant the company recognizes income from deferred income.

In December 1, 2023 the Company received an the second $500,000 of the Quickfire grant mentioned above. The Company initially recorded the proceeds in deferred income. As work was commenced under the grant the company recognizes income from deferred income.

The Company recognized income of approximately $431,000 and $0 in the years ended December 31, 2023 and 2022, respectively. The Company had approximately $669,000 and $0 in deferred income balances related to these grants for the years ended December 31, 2023 and 2022, respectably.

NOTE 11 – SHAREHOLDERS' EQUITY (DEFICIT)

As of December 31, 2023, the total authorized capital stock of the Company was 8,000,000 shares, which consisted of 5,000,000 shares of Common Stock, $0.001 par value per share; 1,000,000 shares of Nonvoting Common Stock $0.001 par value per share; 2,000,000 shares of Preferred Stock, $0.001 par value per share.

Common stock

At December 31, 2023 and 2022, the Company has authorized 5,000,000 shares of Common Stock, par value $0.001 per share, of which, 1,287,930 were issued.

General

The voting, dividend and liquidation rights of the holders of shares of Common Stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. The Common Stock has the following characteristics:

Voting

The holders of shares of Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders and written actions in lieu of meetings.

Dividends

The holders of shares of Common Stock are entitled to receive dividends, if and when declared by the board of directors. Cash dividends may not be declared or paid to holders of shares of Common Stock until paid on each series of outstanding preferred stock in accordance with their respective terms. As of December 31, 2023, no dividends have been declared or paid since the Company's inception.

Liquidation

After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of the Common Stock are entitled to share ratably in the Company's assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

Preferred stock

At December 31, 2023 and 2022, the Company authorized 2,000,000 shares of $0.001 per share par value preferred stock, of which none have been issued.

Nonvoting Common stock

At December 31, 2023 and 2022, the Company authorized 1,000,000 shares of $0.001 per share par value Nonvoting Common Stock, of which, none have been issued.

General

The voting, dividend and liquidation rights of the holders of shares of Nonvoting Common Stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. The Nonvoting Common Stock has the following characteristics:

Voting

The holders of shares of Nonvoting Common Stock are not entitled to vote. Only in special and limited case where mandated by Delaware law, Nonvoting shareholders shall be entitled to one half (½) vote for each share of Nonvoting Common Stock.

Dividends

The holders of shares of Nonvoting Common Stock are entitled to receive dividends on a one for one basis, if and when declared by the board of directors on Common Stock. Cash dividends may not be declared or paid to holders of shares of Nonvoting Common Stock until paid on each series of outstanding preferred stock in accordance with their respective terms. For the years ended December 31, 2023 and 2022, no dividends have been declared or paid since the Company's inception.

Liquidation

After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of the Nonvoting Common Stock are entitled to share ratably in the Company's assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

Warrants

As noted in Note 4, Senior Secured Convertible Promissory Notes, the Company issued an additional 88,826 warrant shares during the year ended December 31, 2022. As of December 31, 2023 these warrants have not been exercised and remain outstanding.

	Warrants	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2021	143,266	$ 10.47	5.50
Granted	88,826	10.47	
Forfeited/Cancelled	—	—	
Outstanding at December 31, 2022	232,092	$ 10.47	4.50
Granted	—	—	
Forfeited/Cancelled	—	—	
Outstanding at December 31, 2023	**232,092**	**$ 10.47**	**3.50**

As of December 31, 2023, outstanding warrants expire in June 19, 2027, and have a fair value of $382,000.

NOTE 12 – INCOME TAXES

Significant components of the Company's deferred tax assets and liabilities at December 31, 2023 and December 31, 2022 are as follows:

(table in thousands)	2023	2022
Net operating losses	$ 1,116,404	$ 729,814
Accrued Expenses and Other	31,582	13,699
R&D Credit Carryforward	20,004	10,001
R&D Capitalization	710,455	370,551
Nondeductible Interest Expense	433,989	111,199
Other	(11,897)	(38,694)
Total gross deferred tax assets/(liabilities)	**$ 2,300,537**	**$ 1,196,570**
Less valuation allowance	(2,300,537)	(1,196,570)
Net deferred tax assets/(liabilities)	**$ —**	**$ —**

The income tax benefit for the years ended December 31, 2023 and December 31, 2022 differed from the amounts computed by applying the U.S. federal income tax rate of 21% to loss before tax benefit as a result of nondeductible expenses, tax credits generated, utilization of net operating loss carryforwards, and increases in the Company's valuation allowance.

(table in thousands)	2023	2022
Federal Statutory Rate	$ (1,958,993)	$ (780,285)
State Income Tax, Net of Federal Benefit	(992)	(992)
Permanent Differences	1,150,417	197,715
Stock Based Compensation	14,802	67
Research and Development	(571,473)	(350,803)
Change in Valuation Allowance	1,366,239	934,298
Effective Tax	$ —	$ —

A valuation allowance is required to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of the available evidence, both positive and negative, the Company determined that valuation allowances of $2,300,537 and $1,196,570 at December 31, 2023 and December 31, 2022 were necessary to reduce the deferred tax assets to the amount that will more likely than not be realized.

At December 31, 2023 and 2022, the Company had gross U.S. Federal income tax net operating loss ("NOL") carryforward of approximately $2,067,595 and $883,348, respectively that may be used to offset future taxable income. The NOL was generated after 2017 and can be carried forward indefinitely under the Tax Cuts and Jobs Act. The company also had gross $2,052,767 of state net operating losses that will begin to expire in 2038. At December 31, 2023, the Company had approximately $12,662 of federal Research and Development (R&D) tax credit carry-forwards. If not utilized, the federal R&D credits will begin to expire in 2042.

The Internal Revenue Code (the "IRC") contains limitations on the use of net operating loss carryforwards after the occurrence of a substantial ownership change as defined by IRC Section 382. The Company has not performed a detailed analysis, however utilization of such net operating loss carryforwards will likely be significantly limited due to the shares issued in the Primary Financing and the Merger.

The income tax benefit for the years ended December 31, 2023 and 2022 differed from the amounts computed by applying the US federal income tax rate of 21% primarily because of the increase in the valuation allowance and the tax impact of other permanent items, which resulted in an effective tax rate of zero for both years.

The Tax Cuts and Jobs Act of 2017 (TCJA) has modified the IRC 174 expenses related to research and development for the tax years beginning after December 31, 2021. Under the TCJA, the Company must now capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and 15 years for non-U.S. activities using a mid-year convention. Therefore, the capitalization of research and development costs in accordance with IRC 174 resulted in a gross deferred tax asset of $3,206,283.

NOTE 13 - CONTINGENCIES

From time to time, the Company may become involved in various legal matters arising in the ordinary course of business. Management is unaware of any matters requiring accrual for related losses in the financial statements.

NOTE 14 - SUBSEQUENT EVENTS

Management has evaluated subsequent events through November 26, 2024, which is the date the financial statements were available to be issued. Other than disclosed below, there were no subsequent events that require adjustment or disclosure in the consolidated financial statements.

Between May 2024 and September 2024, the Company issued $655,555 of notional principal of promissory notes with an original issue discount of 10%, an annual interest rate of 10%, and a maturity date of 180-days from issuance to a series of investors. In connection with the issuance of these notes, the Company issued to the holders of the notes an aggregate of 89,000 warrants to purchase shares of the Company's Common Stock at a price of $16.00 per share, with a term of 5 years from the date of issue. Additionally, as compensation for investment banking services the company issued 45,542 warrants to purchase shares of the Company's Common Stock to Sutter Securities and related parties at a range of prices with a weighted average purchase price of $11.61.

On October 30, 2024, the Company issued convertible notes with principal amount of $250,000, with a Company option to call an additional $250,000 under equivalent terms. These notes will convert into shares of the Company's Common Stock at a price of $5.23 per share in a manner substantially similar to the conversion rights under the Senior Secured Convertible Notes described above, have an annual interest rate of 10%, and a maturity date 180 days from the date of issuance.

During the second half of 2024, founders of the Company loaned the Company approximately $100,000 through non-interest bearing, open-ended maturity notes.

DECOY THERAPEUTICS, INC.
Consolidated Balance Sheets

	September 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,198,684	$ 4,156,433
Prepaid expenses and other current assets	182,171	194,664
Total current assets	3,380,855	4,351,097
Fixed assets, net of depreciation	71,239	105,450
Other assets - long term	40,000	41,000
Total assets	$ 3,492,094	$ 4,497,547
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 837,234	$ 400,495
Accrued expenses	307,890	185,024
Accrued interest and financing expense	2,377,217	1,541,863
Deferred income - grants	3,192,636	4,077,453
Shareholder note	117,873	—
Promissory note	2,150,568	1,425,939
Convertible note - seed tranche A	4,382,000	4,122,000
Convertible note - seed	1,093,000	1,073,000
Convertible note - senior	6,746,562	6,523,556
Total current liabilities	21,204,980	19,349,330
Warrants	305,465	131,000
Total liabilities	$ 21,510,445	$ 19,480,330
Commitments and contingencies	—	—
Shareholders' equity:		
authorized -0- shares issued and outstanding at September 30, 2024 authorized -0- shares issued and outstanding at September 30, 2024 and December 31, 2023.		—
Common stock; par value $.001 per share; 6,000,000 shares authorized (includes 1,000,000 non-voting shares) at September 30, 2024 and December 31, 2023; 1,287,930 shares issued and outstanding at September 30, 2024 and December 31, 2023.	1,288	1,288
Additional paid in capital	292,772	74,512
Accumulated deficit	(18,312,411)	(15,058,583)
Total shareholders' equity (deficit)	$ (18,018,351)	$ (14,982,783)
Total liabilities and shareholders' equity	$ 3,492,094	$ 4,497,547

The accompanying footnotes are an integral part of these consolidated financial statements

DECOY THERAPEUTICS, INC.
Consolidated Statements of Operations (Unaudited)

	Nine months ended September 30,	
	2024	**2023**
Operating expenses		
General and administrative	$ 872,415	$ 710,971
Research and development	1,925,148	1,662,456
Total operating expenses	$ 2,797,563	$ 2,373,427
Other (income) and expenses		
Grant income	$ (1,134,817)	$ (307,997)
Fair value adjustment to convertible notes payable	406,000	2,604,000
Warrant liability (income) expense	174,465	—
Financing expense	97,007	28,993
Unrealized loss (gain)	517	—
Interest expense	913,093	1,231,402
Total other (income) expense	456,265	3,556,399
Net loss	$ (3,253,828)	$ (5,929,826)
Net loss attributable to shareholders - per share		
Basic	$ (2.53)	$ (4.60)
Fully-diluted	$ (2.53)	$ (4.60)
Weighted average number of common shares		
Basic	1,287,930	1,287,930
Fully-diluted	1,287,930	1,287,930

The accompanying footnotes are an integral part of these consolidated financial statements

DECOY THERAPEUTICS, INC.
Consolidated Statements of Shareholders' Equity (Unaudited)

Nine months ended September 30, 2023

	Preferred Shares		Common Shares		Additional Paid in	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	—	$ —	1,287,930	$ 1,288	$ 4,026	$ (5,730,044)	$ (5,724,730)
Stock based compensation	—	—	—	—	448	—	448
Net loss	—	—	—	—	—	(5,929,826)	(5,929,826)
Balance at September 30, 2023	—	$ —	1,287,930	$ 1,288	$ 4,474	$ (11,659,870)	$ (11,654,108)

Nine months ended September 30, 2024

	Preferred Shares		Common Shares		Additional Paid in	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance at December 31, 2023	—	$ —	1,287,930	$ 1,288	$ 74,512	$ (15,058,583)	$ (14,982,783)
Stock based compensation	—	—	—	—	218,260	—	218,260
Net loss	—	—	—	—	—	(3,253,828)	(3,253,828)
Balance at September 30, 2024	—	$ —	1,287,930	$ 1,288	$ 292,772	$ (18,312,411)	$ (18,018,351)

The accompanying footnotes are an integral part of these consolidated financial statements

DECOY THERAPEUTICS, INC.
Consolidated Statements of Cash Flows (Unaudited)

	Nine months ended September 30, 2024	2023
Cash flows (used in) provided by operating activities:		
Net loss	$ (3,253,828)	$ (5,929,825)
Depreciation and amorization	131,217	61,637
Fair value adjustment to convertible notes payable	406,000	2,604,000
Change in fair value of warrant liability	174,465	—
Stock based compensation	218,260	448
Non-cash interest expense related to notes	1,010,100	1,260,455
Changes in assets and liabilities:		
Increase in prepaid expenses & other assets	13,493	(21,611)
Increase in accounts payable and accrued expenses	571,806	(41,678)
Increase (decrease) in deferred revenue - grants	(884,817)	3,792,002
Net cash (used in) provided by operating activities	$ (1,613,304)	$ 1,725,428
Cash flows provided by (used in) investing activities:		
Purchase of property, plant and equiptment	$ —	$ (4,473)
Net cash provided by (used in) investing activities	$ —	$ (4,473)
Cash flows provided by financing activities:		
Proceeds from notes, (net)	$ 537,682	$ 666,324
Increase in due to officers	117,873	—
Net cash provided by financing activities	$ 655,555	$ 666,324
Net change in cash and cash equivalents:	(957,749)	2,387,278
Cash and cash equivalents - beginning of year	4,156,433	1,624,242
Cash and cash equivalents - end of year	$ 3,198,684	$ 4,011,520
Supplemental cash flow disclosures:		
Income taxes paid	$ 6,400	$ 220

The accompanying footnotes are an integral part of these consolidated financial statements

NOTE 1 – ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Decoy Therapeutics, Inc. (the "Company") is a development stage biopharmaceutical company with a mission to revolutionize the design, development, and commercialization of peptide-conjugate therapeutics. The Company believes that its evolving, proprietary ***I***mmediate ***P***eptide/***P***PMO/***P***NA ***A***lpha-helical ***C***onjugate ***T***echnology (IMP^{3}ACT) platform represents a fundamental revolution in peptide-conjugate drug discovery by substantially accelerating the time to design and validate new lead quality drug candidates from years to months or even weeks. The Company's IMP^{3}ACT platform tames the complexity of the peptide-conjugate modality by using machine learning (ML) and artificial intelligence (AI), coupled with world-leading high-speed synthesis of peptide-conjugates and a strong understanding of target biology, to rapidly interrogate and reengineer naturally existing peptides that bind to disease mediating targets.

The Company employs a multi-parameter approach to design and optimization, simultaneously focusing on a broad set of characteristics that will be important through the development and commercialization of the drug, such as chemical affinity, agonist/antagonist activity, enzymatic resistance for enhanced pharmacokinetics, formulation, and manufacturing. The Company believes its approach will significantly decrease timelines, risk, and expense downstream in the therapeutic development process, and can still be executed quickly by the IMP^{3}ACT platform during the design and lead optimization phase.

The Company plans to deploy the IMP^{3}ACT platform in two major target areas: (a) antiviral fusion inhibitors and (b) G-Protein Coupled Receptors (GPCRs). In both target areas there is strong evidence that single peptide-conjugates can be designed to affect multiple disease states, creating the potential for multi-indication therapeutics with broad activity from a single drug. The Company believes both target areas also offer substantial commercial opportunities to address significant unmet medical needs.

The Company was incorporated in Delaware on April 17, 2020 and has a principal place of business in Cambridge, Massachusetts. The Company has a wholly-owned Canadian subsidiary, Decoy Drug Discovery Canada, which was incorporated on July 8, 2021. The Company's Canadian subsidiary's primary activities have been related to sponsored research activities at the University of Toronto and The University of Waterloo.

The Company is devoting substantially all of its efforts to product research and development, initial market development, and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early stage life science companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products, and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the industry, including rapid technological change, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, and dependence on key individuals.

Going Concern Evaluation:

As of September 30, 2024, the Company's primary source of liquidity is its cash and cash equivalent balances. Until the Company is successful in gaining regulatory approvals, it is unable to sell the Company's product in any market. Without revenues, the Company is reliant on funding obtained from investment in the Company to maintain business operations until the Company can generate positive cash flows from operations. The Company cannot predict the extent of future operating losses and accumulated deficit, and it may never generate sufficient revenues to achieve or sustain profitability.

The Company has generated an accumulated deficit of $18.3 million since its inception and will require substantial additional capital to fund its research and development and ongoing operating expenses. It is subject to risks common to companies in the biotechnology industry, including, but not limited to, development by the Company or its competitors of technological innovations, risks of failure of clinical studies, dependence on key personnel, protection of proprietary technology and compliance with government regulations. If access to capital is not achieved in the near term, it will materially harm the Company's business, financial condition and results of

operations to the extent that the Company may be required to cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

NOTE 2 - LIQUIDITY RISKS AND OTHER UNCERTAINTIES

The unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP"). The Company has incurred net losses every year since inception and has an accumulated deficit of approximately $18.3 million at September 30, 2024. The Company has historically funded its operations through debt and equity financings. At September 30, 2024, the Company had cash balances totaling $3.2 million.

The Company will need to arrange additional financing in order to continue to pursue its current business objectives as planned and to continue to fund its operations. The Company is looking to raise additional funds through any combination of additional equity and debt financings or from other sources, however, the Company has no guaranteed source of capital that will sustain operations for a period of one year from the date these financial statements are available to be issued. There can be no assurance that any such potential financing opportunities will be available on acceptable terms, if at all.

Other risks and uncertainties:

The Company is subject to risks common to development stage biopharmaceutical companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, pre-clinical and clinical trial outcome risks, regulatory approval risks, uncertainty of market acceptance and additional financing requirements.

The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products.

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation:

The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. GAAP for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited consolidated financial statements of the Company as of September 30, 2024 and for the nine months then ended. The results of operations for the nine months ended September 30, 2024 are not necessarily indicative of the operating results for the year or any other period. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements and related disclosures as of December 31, 2023 and for the year then ended.

Principles of Consolidation:

The accompanying consolidated financial statements include the accounts of Decoy Therapeutics, Inc. and its wholly owned subsidiary. All intercompany transactions and balances are eliminated in consolidation. The functional currency of Decoy Drug Discovery Canada, Inc., a wholly-owned subsidiary of the Company, is the U.S. dollar. Consolidated balance sheet accounts of the Company's subsidiary are remeasured into U.S. dollars using the exchange rate in effect at the consolidated balance sheet date while expenses are remeasured using the average

exchange rate in effect during the period. Gains and losses arising from remeasurement of the wholly owned subsidiary's financial statements are included in the determination of net loss.

Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and cash equivalents:

The Company considers all highly liquid investments and short-term debt instruments with original maturities of three months or less to be cash equivalents. From time to time during the periods presented, the Company has had bank account balances in excess of federally insured limits where substantially all cash is held in the United States. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Fair value of financial instruments:

The Company considers its cash and cash equivalents, accounts payable, accrued expenses to meet the definition of financial instruments. The carrying amounts of these financial instruments approximated their fair values due to the short maturities.

The Company measures fair value as required by ASC Topic 820, Fair Value Measurements and Disclosures ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (see Note 5).

Property and equipment:

Property and equipment are recorded at cost and are depreciated when placed in service using the straight-line method based on their estimated useful lives as follows:

	Estimated Useful Life
Laboratory equipment	5 years
Computer equipment and software	3 years
Office furniture and equipment	5 years

For the nine months ended September 30, 2024 and 2023, the Company's had property and equipment depreciation expense of approximately $34,000 and $33,000, respectfully.

Impairment of long-lived assets:

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded during the nine months ended September 30, 2024 and 2023.

Warrants:

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net- share settlement), provided that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (a) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control) or (b) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The Company assesses classification of its warrants and other free-standing derivatives at each reporting date to determine whether a change in classification between assets, liabilities and equity is required. The Company evaluated its issued and outstanding warrants to assess their proper classification using the applicable criteria enumerated under U.S. GAAP and determined that such warrants meet the criteria for liability classification in the accompanying consolidated balance sheets as of September 30, 2024 and December 31, 2023, respectively.

Grant income:

The Company has received grants from two funding sources, including a private not-for-profit organization and a federal agency. Grant income consists of income earned from grants to conduct development research. Funds received in advance of services being performed are recorded as deferred income. Income under the not-for-profit and federal agency grants is recognized as labor and material costs are incurred. Labor costs are recognized based on actual salary costs incurred related to the projects, and material costs are recognized based on actual expenditures. As of September 30, 2024 and 2023, the Company has recognized an approximate total of $2.6 million and $1.1 million of income related to these grants, and has received a total of $5.8 million and $5.0 million in cash receipts.

Research and development:

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues costs incurred by external service providers, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

Key Relationships & Licenses:

In June 2020, the Company entered into a one-year, non-exclusive licensing agreement with the Massachusetts Institute of Technology ("MIT") related to developing potential treatments for Covid-19 using a variety available resources, services and technologies from MIT. Additionally, in July 2020, the Company entered into a Sponsored Research Agreement and option agreement with Columbia University to evaluate a molecule to block the transmission of Covid-19, Neither collaboration remains active.

The Company has attracted non-dilutive investments from the European Union's IMI-CARE Consortium, The Bill & Melinda Gates Foundation ("BMGF"), The U.S. Government's Biological Research and Development Authority ("BARDA") and Johnson & Johnson through the U.S. Government's Blue Knight Blue Knight Program.

Stock based compensation:

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model, net of actual forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

The Company utilizes the simplified method to estimate the expected term. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield was assumed to be zero as the Company has not paid and dividends since its inception and does not anticipate paying dividends in the foreseeable future.

Earnings (loss) per share:

The Company reports loss per share in accordance with ASC 260-10, *Earnings Per Share*, which provides for calculation of "basic" and "diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing net income or loss available to shareholders by the weighted average shares outstanding for the period. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. The calculation of diluted net earnings (loss) per share gives effect to ordinary shares equivalents; however, potential shares are excluded if their effect is anti-dilutive.

For the nine months September 30, 2024, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 355,263 shares, 1,042,518 shares from the conversion of outstanding convertible notes and outstanding stock options to purchase 266,950 shares. For the nine months ended September 30, 2023, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 232,092 shares, 942,263 shares from the conversion of outstanding convertible notes and outstanding stock options to purchase 268,200 shares. The inclusion of these warrants, shares from convertible notes and stock options for both the nine months ended September 30, 2024 and 2023 in the denominator would be anti-dilutive.

NOTE 4 – NOTES

Unsecured Promissory Note

In October 20, 2021, the Company issued an unsecured promissory note (the "2021 Promissory Note") in exchange for cash proceeds of $250,000. The term of the 2021 Promissory Note is nine months unless earlier settled upon an automatic payment condition, as further described below. The specific terms and conditions are as follows:

1. **Interest**: Interest of $25,000 shall accrue on the outstanding principal amount for the first 90 days of the loan and thereafter interest shall accrue on $275,000 at a rate per annum equal to 5% compounded each month thereafter until paid.

2. **Automatic Payment:** If at any time during the term of the 2021 Promissory Note the Company had issued and sold $650,000 or more in additional capital exclusive of the 2021 Promissory Note and via the sale of the Company's common stock, $0.001 par value per share (the "Common Stock") or any securities convertible into Common Stock (such event being an "Automatic Payment Date"), then the Company would be required to pay the holder the entire outstanding principal amount within fifteen days after the closing of the relevant transactions. If the Automatic Payment Date occurred before 90 days from the date of the 2021 Promissory Note, then interest of $25,000 would immediately accrue on the outstanding principal amount on the Automatic Payment Date. No such Automatic Payment Date occurred during the term of the 2021 Promissory Note.

3. **Issuance of Company Equity Securities:** Within 90 days from the date of the Promissory Note, the Company issued 3,930 shares of Common Stock to the holder at a price of $0.013 (representing current fair market value based on the Company's most recent 409A valuation at that time) as additional consideration for extending the loan evidenced by the 2021 Promissory Note.

On January 5, 2022, the Company repaid the 2021 Promissory Note in full, including the $25,000 interest specified above. The 2021 Promissory Note was considered settled at that time.

Accounting Guidance

The 2021 Promissory Note is considered an obligation (or liability) of the Company as prescribed by Accounting Standards Codification ("ASC") 470-10. The Company has elected the fair value option under ASC 825 and ASC 825-10-15-4(a) for the 2021 Promissory Note and will measure the 2021 Promissory Note, as a whole, at fair value, with changes in fair value reported in earnings. As neither ASC 815 nor ASC 825 prescribes the location in which the Company should report fair value changes in the income statement, the Company will elect a policy to present all changes in fair value of the 2021 Promissory Note as a component of interest expense.

The embedded forward found in the 2021 Promissory Note requiring the Company to issue 3,930 shares of its Common Stock does not represent an embedded derivative. Since the contract itself does not permit/require net settlement, the contract cannot be traded on active markets, and the shares underlying the forward are not readily convertible to cash, a separate instrument with the same terms as the embedded forward would not meet the definition of a derivative. This means that the embedded forward does not meet the condition in ASC 815-15-25-1(c) and does not need to be bifurcated from the 2021 Promissory Note. Upon issuance of the shares underlying the forward, the Company will record the cash proceeds received, Common Stock (at par), and additional paid in capital.

SEED Tranche A Convertible Promissory Note

On November 4, 2020, the Company entered into a Convertible Promissory Note ("Tranche A Note") in exchange for $250,000 cash proceeds. The Tranche A Note bears interest at 5% per annum computed on a 356-day year. The stated maturity date of the Tranche A Note is December 31, 2021, though this was subsequently amended on February 28, 2022 to extend the maturity date through April 12, 2023, and again amended on November 13, 2023 to extend the maturity date through June 30, 2024.

The Tranche A Note contains a variety of variable share settlement provisions, as indicated below:

Elective Conversion. In the event that the Company issues and sells shares of its equity securities to investors (a "Subsequent Financing"), then the holder of the Tranche A Note shall have the rights and option to convert the outstanding principal amount of the Tranche A Note and any unpaid accrued interest in whole into the equity securities sold in the Subsequent Financing at a conversion price equal to the lowest of the following: (i) the cash price paid per share for equity securities by the investors in the Subsequent Financing; (ii) $0.8333334 per share (equitably adjusted to account for stock splits, stock dividends and similar events with respect to the Common Stock between the date of the Tranche A Note and the date of such conversion); and (iii) the lowest exercise or conversion price per share of Common Stock underlying any stock option, stock appreciation right, or other stock-based equity award under the Company's stock-based awards (the "Stock Plan"). The issuance of equity securities pursuant to the conversion of this Tranche A Note shall otherwise be upon and subject to the same terms and conditions applicable to equity securities sold in the Subsequent Financing.

Automatic Conversion upon a Qualified Financing. In the event that the Company issues and sells shares of its equity securities to investors while the Tranche A Note remains outstanding in an equity financing with total proceeds to the Company of not less than $5,000,000, excluding the conversion of the Tranche A Note or other convertible securities issued for capital raising purposes (a "Qualified Financing"), then the outstanding principal amount of the Tranche A Note and any unpaid accrued interest shall automatically convert in whole without any further action by the holder into equity securities sold in the Qualified Financing at a conversion price equal to the lowest of the following: (i) the cash price paid per share for equity securities by the investors in the Qualified Financing; (ii) $0.8333334 per share (equitably adjusted to account for stock splits, stock dividends and similar events with respect to the Company's Common Stock between the date of the Tranche A Note and the date of such conversion); and (iii) the lowest exercise or conversion price per share of Common Stock underlying any stock option, stock appreciation right, or other stock-based equity award under the Company's Stock Plan, in each case granted to any of the current four stockholders of the Company between the date of the Tranche A Note and the date of such conversion (as equitably adjusted as provided in clause (ii) above). The issuance of equity securities pursuant to the conversion of this Tranche A Note shall otherwise be upon and subject to the same terms and conditions applicable to equity securities sold in the Qualified Financing.

Change of Control. If the Company consummates a change of control (as further defined below) while the Tranche A Note remains outstanding, the Company shall repay the holder in cash in an amount equal to the outstanding principal amount of this Tranche A Note plus any unpaid accrued interest on the original principal; provided, however, that upon the written election of the holder made not less than five days prior to such change of control, the Company shall convert the outstanding principal balance of this Tranche A Note and any unpaid accrued interest into shares of Common Stock at a conversion price equal to the lower of the following: (i) $0.8333334 per share (equitably adjusted to account for stock splits, stock dividends and similar events with respect to the Common Stock between the date hereof and the date of such conversion); and (ii) the lowest exercise or conversion price per share of Common Stock underlying any stock option, stock appreciation right, or other stock-based equity award under the Company's Stock Plan, in each case granted to any of the current four stockholders of the Company between the date hereof and the date of such conversion (as equitably adjusted as provided in clause (i) above). For purposes of the Tranche A Note, a change of control means (i) a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the shares of capital stock of the Company immediately prior to such consolidation, merger or reorganization continue to represent a majority of the voting power of the surviving entity immediately after such consolidation, merger or reorganization; (ii) any transaction or series of related transactions to which the Company is a party in which in excess of 50% of the Company's voting power is transferred; or (iii) the sale or transfer of all or substantially all of the Company's assets, or the exclusive license of all or substantially all of the Company's material intellectual property; provided that a change of control shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Company or any successor, indebtedness of the Company is cancelled or converted or a combination thereof.

Neither party has the ability to redeem the Tranche A Note prior to the stated maturity date and there are no other provisions requiring accounting analysis.

The Tranche A Note is considered an obligation (or liability) of the Company as prescribed by ASC 470-10 and/or 480-10-25-14(a).). The Company has elected the fair value option under ASC 825-10-15-4(a) and paragraphs 4-5 of ASC 815-15-25 for each Tranche A Note and will instead measure each Tranche A Note, as a whole, at fair value, with changes in fair value reported in earnings. The Company will present all changes in fair value of the Tranche A Note as a component of interest expense. For the nine months ended September 30, 2024 and 2023, the Company recorded approximately $9,300 and $9,300 respectively, of accrued interest related to the Tranche A Note. For the nine months ended September 30, 2024 and 2023, the Company recorded income (expense) approximately of ($260,000) and ($1,927,000), respectively, as a change in the fair value of debt in the statement of operations.

SEED Convertible Promissory Notes

On March 25, 2021, April 12, 2021, and April 5, 2022, the Company entered into three separate Convertible Promissory Notes (the "Seed Notes") in exchange for $650,000 total cash proceeds. The Seed Notes bear interest at 8% per annum computed on a 365-day year. The stated maturity date of each Seed Note is two years (24 months) after the Issuance Date. The maturity date of the April 5, 2022 Seed Note has been extended to December 31, 2024. The maturity dates of the March 25, 2021 and April 12, 2021 Seed Notes have been extended to June 30, 2024. At the time of issuance of these financials, the Company is in process of further extending the maturity dates for the March 25, 2021 and April 12, 2021 Seed Notes. The Seed Notes are considered an obligation (or liability) of the Company as prescribed by ASC 470-10 and/or 480-10-25-14(a). The Company has elected the fair value option under ASC 825-10-15-4(a) and paragraphs 4-5 of ASC 815-15-25 for each Seed Note and will instead measure each Seed Note, as a whole, at fair value, with changes in fair value reported in earnings. The Seed Notes are convertible at the option of the Holder subject to the following conditions which are identical across the three Seed Notes:

Conversion upon a Qualified Financing. In the event that the Company issues and sells shares of its equity securities to investors while the Seed Notes remain outstanding in an equity financing with total proceeds to the Company of not less than $5,000,000 (excluding the conversion of the Seed Notes or other convertible securities issued for capital raising purposes (a "Seed Note Qualified Financing"), then the outstanding principal amount of the Seed Notes and any unpaid accrued interest shall automatically convert in whole without any further action by the

holders into equity securities sold in the Seed Note Qualified Financing at a conversion price equal to the lesser of (i) the cash price paid per share for equity securities by the investors in the Seed Notes Qualified Financing multiplied by 0.80, and (ii) the quotient resulting from dividing $20,000,000 by the number of outstanding shares of Common Stock of the Company immediately prior to the Seed Note Qualified Financing (assuming conversion of all securities convertible into Common Stock and exercise of all outstanding options and warrants, but excluding the shares of equity securities of the Company issuable upon the conversion of Seed Notes or other convertible securities issued for capital raising purposes. The issuance of equity securities pursuant to the conversion of the Seed Notes shall be upon and subject to the same terms and conditions applicable to equity securities sold in the Seed Note Qualified Financing. If the conversion price of the Seed Notes is less than the price per share at which equity securities are issued in the Seed Note Qualified Financing, the Company may, solely at its option, elect to convert the Seed Notes into shares of a newly created series of preferred stock having the identical rights, privileges, preferences and restrictions as the equity securities issued in the Seed Note Qualified Financing, and otherwise on the same terms and conditions, other than with respect to: (i) the per share liquidation preference and the conversion price for purposes of price-based anti-dilution protection, which will equal the conversion price; and (ii) the per share dividend, which will be the same percentage of the conversion price as applied to determine the per share dividends of the investors in the Seed Note Qualified Financing relative to the purchase price paid by the investors.

Optional Conversion at non-Qualified Financing. In the event the Company consummates, while this Seed Notes remain outstanding, an equity financing pursuant to which the Company sells shares of preferred stock in a transaction that does not constitute a Seed Note Qualified Financing, then the Seed Note holders shall have the option to treat such equity financing as a Seed Note Qualified Financing on the same terms set forth herein.

Maturity Date Conversion. In the event that the Seed Notes remain outstanding on the maturity sate, then the outstanding principal balance of the Seed Notes and any unpaid accrued interest shall automatically without any further action by the holders convert as of the maturity date into shares of Common Stock at a conversion price equal to the quotient resulting from dividing $20,000,000 by the number of outstanding shares of Common Stock as of the maturity date assuming conversion of all securities convertible into Common Stock and exercise of all outstanding options and warrants, but excluding the shares of equity securities of the Company issuable upon the conversion of the Seed Notes or other convertible securities issued for capital raising purposes.

Change of Control. If the Company consummates a change of control (as further defined below) while the Seed Notes remain outstanding, the Company shall repay the holders in cash in an amount equal to the outstanding principal amount of the Seed Notes plus any unpaid accrued interest on the original principal; provided, however, that upon the written election of the holders made not less than five days prior to the change of control, the Company shall convert the outstanding principal balance of the Seed Notes and any unpaid accrued interest into shares of Common Stock at a conversion price equal to the quotient resulting from dividing $20,000,000 by the number of outstanding shares of Common Stock of the Company immediately prior to the change of control. For purposes of the Seed Notes, a change of control means (i) a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the shares of capital stock of the Company immediately prior to such consolidation, merger or reorganization continue to represent a majority of the voting power of the surviving entity immediately after such consolidation, merger or reorganization; (ii) any transaction or series of related transactions to which the Company is a party in which in excess of 50% of the Company's voting power is transferred; or (iii) the sale or transfer of all or substantially all of the Company's assets, or the exclusive license of all or substantially all of the Company's material intellectual property.

The Seed Notes contain as side letter that contains participation and put rights. Aside from the conditions noted in the side letter, neither party has the ability to redeem the loan prior to the stated maturity date and there are no other provisions requiring accounting analysis.

For the nine months ended September 30, 2024 and 2023 the Company recorded approximately $39,000 and $39,000 of accrued interest. For the nine months ended September 30, 2024 and 2023 the Company recorded income (expense) related to the Seed Notes of approximately of ($20,000) and ($218,000), respectively as a change in the fair value of debt in the Statement of Operations.

Senior Secured Convertible Promissory Notes

On December 22, 2021, and December 23, 2021, the Company entered into two separate Senior Secured Convertible Promissory Notes (the "Senior Notes") in exchange for up to a combined $4M total cash proceeds. The stated maturity date for each Senior Note is March 22, 2023, and March 23, 2023, respectively. Per an amendment dated March 22, 2023, the Company elected to extend the maturity date for an additional six months for both Senior Notes. The Company subsequently extended the maturity date for both Senior Notes to June 30, 2024. At the time of issuance of these financials, the Company is working on an updated extension to these Senior Notes. The Senior Notes are considered an obligation (or liability) of the Company as prescribed by ASC 470-10 and/or 480-10-25-14(a). The Company has elected the fair value option under ASC 825-10-15-4(a) and paragraphs 4-5 of ASC 815-15-25 for each Senior Note and will instead measure each Senior Note, as a whole, at fair value, with changes in fair value reported in earnings.

The Senior Notes contain an option to extend the maturity date by an additional six months for an extension premium of 110% which is exercisable by the issuer. The Senior Notes bear interest at 12% per annum computed on a 360-day year and contain the following conversion and redemption features:

At any time after the issuance sate of the Senior Notes, the Senior Notes shall be convertible into validly issued, fully paid and non-assessable shares of Common Stock. The number of shares of Common Stock issuable upon conversion of any conversion amount, including all accrued and unpaid interest with respect to such portion of the principal amount, divided by the conversion amount. The conversion amount attributable to the first disbursement conversion price (initially $10.47). If a subsequent disbursement is made in a six month period following the issuance date, initially 110% of the first disbursement conversion price, or if a subsequent disbursement is made after the six month period following the issuance date but prior to the date that is one year from the issuance date, initially 125% of the first disbursement conversion price. From and after a date upon which the Company becomes a publicly traded entity (as defined in the Senior Note), the Company shall not implement the conversion of any portion of the Senior Notes, and the holders shall not have the right to convert any portion of the Senior Notes.

The Company issued the Senior Notes together with detachable warrants (the "Warrants") to purchase shares of the Company's Common Stock pursuant to a warrant purchase agreement. The Warrants were issued after each scheduled disbursement. The Company believes that the Warrants issued in connection with the Senior Notes are liability- classified under ASC 480-10-25-8, because the Company could be required to repurchase the Warrants under the terms thereof for reasons outside the control of the Company, including in the event of default (as defined in the Warrants). Even if the Warrants were not liability-classified under ASC 480, they would be classified as liabilities under ASC 815 because the Warrants meet the definition of a derivative under ASC 815-10-15-8. Because the Warrants are liability-classified, they will be initially and subsequently measured at fair value until settlement or expiry, with changes in fair value reported in the Statement of Income. The Company will also be measuring the related Senior Notes issued in conjunction with the Warrants at fair value. To the extent that the proceeds received from investors are less than the combined fair values of the Senior Notes and Warrants, the difference will be reported as an immediately loss in the statement of operations. For the nine months ended September 30, 2024 and 2023 the Company recorded income (expense) approximately of ($174,000) and $0 as a change in the fair value of warrant in the Statement of Operations.

Finally, in connection with the issuance of the Senior Notes, the Company also entered into a Registration Rights Agreement (the "RRA") that outlines the actions the Company will take to register the securities underlying the Senior Notes and Warrants with the U.S, Securities and Exchange Commission. If the Company does not comply with the registration requirements under the RRA, the holders are entitled to receive payments if the Company is unable to comply with the promises in the RRA. The Company shall pay to each holder an amount in cash, as partial liquidated damages and not as a penalty, equal to 1% of the purchase price paid by such holder pursuant to the purchase agreement for the Senior Notes. The Company analyzed ASC 825-20-25-1 for the accounting treatment for registration agreements related to financing arrangements. The Company determined the existence of the registration payment arrangement does not affect the accounting for the Senior Notes and the registration payment arrangement should not be recognized at this time under ASC Subtopic 450-20. ASC 450-20-25-1, requires contingent obligations to be recorded when a loss is probable of occurrence and reasonably estimable. As of December 31,

2023, it is not probable that the Company will be subject to penalties related to the RRA. The Company will reassess this conclusion each reporting period.

For the nine months ended September 30, 2024 and 2023 the Company recorded approximately $655,000 and $360,000 of accrued interest related to the SSCPN. For the nine months September 30, 2024 and 2023 the Company recorded income (expense) approximately of ($201,000) and ($476,000) as a change in the fair value of debt in the Statement of Operations. At origination the Company incurred $45,000 of dept issuance cost related to these SSCPN, during the nine months ended September 30, 2024 and 2023 the company amortized $0 and $16,875 of these costs.

Bridge Notes

During the year ended December 31, 2023, the Company entered into a series of Promissory Notes ("Bridge Notes") in exchange for notional proceeds totaling $1,448,899. The terms and conditions of each Bridge Note are identical except for the proceeds invested by each investor and the maturity date of each Bridge Note. The stated maturity date for these Bridge Notes is twelve months from the date of issuance. At the time of issuance of these financials, the Company is working on an updated extensions to these Bridge Notes.

Each of the Bridge Notes was issued at an original issue discount with principal and accrued interest due and payable on the earlier of one year from issuance date, or the date of the closing of an initial public offering of the Company ("IPO"). The Company also has the option to repay the loan before the stated maturity date without penalty. The securities purchase agreement pursuant to which the Bridge Notes were sold requires that, in addition to repayment of principal and interest, shares of the Company's Common Stock be issued to the holder according to the following conditions: 100% of the principal value of the note divided by (A) the Company's IPO price or (B) if the Company fails to complete an IPO before maturity, the number of shares calculated using a $40 million pre-money valuation for the Company and the number of the Company's shares outstanding at maturity.

Interest shall accrue to the holders on the aggregate then outstanding principal amount of the Bridge Notes at the rate of 10% per annum, calculated on the basis of a 360-day year and shall accrue daily commencing on the original issue date of the Bridge Notes until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts which may become due hereunder, has been made.

The Bridge Notes are obligations of the Company that could be settled in cash (traditional debt under ASC 470) and a variable number of shares as per ASC 480-10-25-14(a). Under either ASC Topic, pursuant to U.S. GAAP the Bridge Notes would be presented the balance sheet as a liability at amortized cost.

The Bridge Notes contain a number of embedded features that should be evaluated for bifurcation. The Company will elect the fair value option to account for each of the Bridge Notes, as permitted by ASC 825-10-15 and ASC 815-15-25.

Based on the Company's analysis, all three conditions under ASC 815-15-25-1 are met and the embedded share settlement feature would ordinarily require bifurcation as an embedded derivative. Based on the conditions in ASC 825-10-15 and ASC 815-15-25, the Company elected to apply the fair value option for each of the Bridge Notes and will not be required to bifurcate any embedded features. Neither ASC 825 nor ASC 815 prescribes the location in which the Company should report fair value changes in the income statement, the Company will elect a policy to present all changes in fair value of the Bridge Notes as a component of interest expense in the Statement of Income.

For the nine months ended September 30, 2024 and 2023 the Company recorded approximately $112,000 and $11,000 of accrued interest related to these Bridge Notes. At origination during the year ended December 31, 2023 the Company incurred $145,000 of dept issuance cost related to these Bridge Notes, during the nine months ended September 30, 2024 the company amortized approximately $97,000 of these costs.

Demand Notes

On June 13, 2023, the Company issued three separate notes ("Demand Notes") in exchange for gross cash proceeds totaling $150,000, prior to the payment of offering costs. The terms and conditions of each Demand Note

are identical. Each Demand Note was issued at a discount and must be repaid upon the earlier of the maturity date or within 5 days of the demand by the holder. The specific terms of the Demand Notes are as follows:

In exchange for receipt of Demand Notes, the Company promises to pay the holders, the principal sum of $166,665 together with interest thereon from the date hereof, at 10% per annum, with interest and principal being immediately payable on the earlier of (i) the maturity date and (ii) five days from the date that the Holder demands repayment. The maturity date shall be 90 days from the issuance date of each Demand Note. At maturity on August 12, 2023 two of these three Demand Notes were repaid in full, the one remaining note is outstanding to an employee/founder of the Company – See related party (Note 9)

The Demand Notes are obligations of the Company that will be settled in cash and therefore represent traditional debt. Traditional debt is accounted for under ASC 470 and requires presentation on the balance sheet as a liability at amortized cost.

The Demand Notes contain an embedded written put right. Specifically, the investors of each Demand Note have the right to demand repayment with five days' notice. The Demand Notes were evaluated to determine whether the embedded features should be bifurcated, or detached from the note and accounted for separately if it meets the criteria in ASC 815-15-25-1. As neither ASC 825 nor ASC 815 prescribes the location in which the Company should report fair value changes in the income statement, the Company elected a policy to present all changes in fair value of the Demand Notes as a component of interest expense in the Statement of Operations. For the nine months ended September 30, 2024 and 2023 the Company recorded approximately $4,100 and $1,600 of accrued interest related to these Demand Notes.

180 Day Promissory Notes

Between May 2024 and September 2024, the Company issued $655,555 of notional principal of promissory notes with an original issue discount of 10%, an annual interest rate of 10%, and a maturity date of 180-days from issuance to a series of investors. In connection with the issuance of these notes, the Company issued to the holders of the notes an aggregate of 89,000 warrants to purchase shares of the Company's Common Stock at a price of $16.00 per share, with a term of 5 years from the date of issue. Additionally, as compensation for investment banking services the company issued 45,542 warrants to purchase shares of the Company's Common Stock to Sutter Securities and related parties at a range of prices with a weighted average purchase price of $11.61. For the nine months ended September 30, 2024 the Company recorded approximately $17,000 of accrued interest related to these notes.

Below is a schedule of note balances as of the nine months ended September 30, 2024:

	180 Day Promissory Notes	Promissory Notes	Seed Tranche A	Seed	Secured Convertible Note
Beginning Balance December 31, 2023	$ —	$ 1,544,444	$ 250,000	$ 650,000	$ 4,000,000
Change in principal balance	655,555	—	—	—	—
Ending Balance September 30, 2024	$ 655,555	$ 1,544,444	$ 250,000	$ 650,000	$ 4,000,000

NOTE 5 - FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company applies fair value accounting for all assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities the Company considers the principal or most advantageous market in which it would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. For certain instruments, including cash and cash equivalents, accounts payable, and accrued expenses, it was estimated that the carrying amount approximated fair value because of the short maturities of these instruments.

Fair value is estimated using various valuation models, which utilize certain inputs and assumptions that market participants would use in pricing the asset or liability. The inputs and assumptions used in valuation models are classified in the fair value hierarchy as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Quoted market prices for similar instruments in an active market; quoted prices for identical or similar assets and liabilities in markets that are not active; and model-derived valuations inputs of which are observable and can be corroborated by market data.

Level 3: Unobservable inputs and assumptions that are supported by little or no market activity and that are significant to the fair value of the asset and liability. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining the appropriate hierarchy levels, the Company analyzes the assets and liabilities that are subject to fair value disclosure. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to their fair value measurement.

The following table presents the Company's liabilities that are measured at fair value on a recurring basis by fair value hierarchy at September 30, 2024 and December 31, 2023:

September 30, 2024	Level 1	Level 2	Level 3	Total
Promissory note	—	—	$ 2,150,568	$ 2,150,568
Seed Tranche A	—	—	4,382,000	4,382,000
Seed	—	—	1,093,000	1,093,000
Senior Secured Convertible Note	—	—	6,746,562	6,746,562
SSCPN Warrant	—	—	305,465	305,465
Total	$ —	$ —	$ 14,677,595	$ 14,677,595

December 31, 2023	Level 1	Level 2	Level 3	Total
Promissory note	—	—	$ 1,425,939	$ 1,425,939
Seed Tranche A	—	—	4,122,000	4,122,000
Seed	—	—	1,073,000	1,073,000
Senior Secured Convertible Note	—	—	6,523,556	6,523,556
SSCPN Warrant	—	—	131,000	131,000
Total	—	—	$ 13,275,495	$ 13,275,495

The following shows the movement of the warrant and note liability balances during the year ended December 31, 2023 and the nine months ended September 30, 2024:

	SSCPN Warrants	Seed Tranche A	Seed	Senior Secured Convertible Note
Beginning Balance December 31, 2023	$ 131,000	$ 4,122,000	$ 1,073,000	$ 6,523,556
Change in principal balance	—	—	—	—
Change in Fair value	174,465	260,000	20,000	223,006
Ending Balance September 30, 2024	$ 305,465	$ 4,382,000	$ 1,093,000	$ 6,746,562

Warrants issued to the Senior Note holders (Note 4) were classified as a liability on issuance.

NOTE 6 – STOCK BASED COMPENSATION

In May 2020, the Company adopted the Decoy Equity Incentive Plan (the "Plan"), pursuant to which the Company may grant incentive stock options ("ISOs"), non-qualified stock options, restricted stock, and stock grants to purchase up to 1,800,000 shares of Common Stock. In December 2023, the Company amended the Plan to increase the number of shares available under the Plan to 2,250,000 shares of Common Stock. Under the Plan, ISOs may not be granted with an exercise price less than fair value of the Company's Common Stock on the date of the grant, and all options generally vest over a four-year period. These options expire ten years after the grant date.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the Plan. Options granted by the Company typically vest over a four year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options are exercisable from the date of grant for a period of ten years. For options granted to date, the exercise price equaled the estimated fair value of the Common Stock as determined by the board of directors on the date of grant.

The following table summarizes stock-based activities under the Amended Plan:

	Options	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2023	469,350	$ 2.03	8.96
Granted	5,000	9.95	
Outstanding at September 30, 2024	**474,350**	**$ 2.11**	**8.22**
Exercisable options at September 30, 2024	345,267	$ 1.43	7.88

The intrinsic value of outstanding options at September 30, 2024 was approximately $893,000.

Stock options granted during the nine months ended September 30, 2024 and the year ended December 31, 2023, were valued using the Black-Scholes option-pricing model with the following weighted average assumptions:

	September 30, 2024	December 31, 2023
Expected volatility	95.1 %	97.9 %
Risk-free interest rate	4.6 %	3.9 %
Expected dividend yield	0.0 %	0.0 %
Expected life of options in years	5.2	5.5
Exercise Price	$ 9.95	$ 3.56
Fair value of common stock	$ 2.40	$ 2.61
Estimate fair value of option	$ —	$ —

Stock based compensation expense was $218,260 ($130,258 included in research and development expense and $88,002 included in general and administrative expenses) in the nine months ended September 30, 2024. Stock based compensation expense was $448 ($126 included in research and development expense and $322 included in general and administrative expenses) in the nine months ended September 30, 2023.

At September 30, 2024, the total unrecognized compensation expense related to non-vested options was approximately $328,000 and is expected to be recognized over the remaining weighted average service period of approximately 1.54 years.

NOTE 7 – PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are as follows:

	September 30, 2024	December 31, 2023
Prepaid R&D costs	$ 86,000	$ 95,360
Prepaid rent	20,446	16,023
Prepaid software subscriptions	16,249	49,828
Prepaid professional fees	51,110	20,000
Prepaid other	8,367	13,453
Total	**$ 182,172**	**$ 194,664**

NOTE 8 – ACCRUED EXPENSES

Accrued expenses are as follows:

	September 30, 2024	December 31, 2023
Payroll	$ 183,867	$ 72,039
Professional fees	86,425	103,071
Other expenses	37,598	9,914
Total	**$ 307,890**	**$ 185,024**

NOTE 9 – RELATED PARTY TRANSACTIONS

Due to Officers/Founders:

As of September 30, 2024, one officer/founder of the Company had an outstanding Demand Note (See Note 4) in the principal amount of $55,555, plus accrued interest of $7,078. This note accrues interest at 10% and has a maturity date of December 28, 2024.

During the second half of 2024, shareholder/founders of the Company loaned the Company approximately $118,000 through non- interest bearing, open-ended maturity notes.

NOTE 10 – LICENSE AGREEMENTS AND GRANTS

The Company has received significant grants are from The Bill and Melinda Gates Foundation, Johnson & Johnson through the U.S. government's Blue Knight Program, the European Union's IMI.CARE.EU Consortium, the Canadian government's National Research Council, and GOOGLE's AI Startup Program.

Key Relationships, Licenses and Grants

The Company received a foundation grant from the Bill and Melinda Foundation for the development of a nasally inhaled, low cost, peptide conjugate *pan-Coronavirus* antiviral inhibitor. The initial award in September 6, 2021 provided up to a total of approximately $904,000 and expired on February 28, 2023. The Company initially recorded the proceeds in Deferred income. As work was commenced under the grant the company recognizes income from deferred income.

In 2023 the Company entered into a supplemental grant with the Bill and Melinda Foundation for an additional $4,084,500 for continued work on the nasally inhaled, low cost, peptide conjugate *pan-Coronavirus* antiviral inhibitor reference above. The Company received payment of $3,500,000 in September 28, 2023, the remaining $584,500 will be received after the completion of certain milestones .

The Company recognized income of approximately $371,000 and $166,000 in the nine months ended September 30, 2024 and 2023, respectively. The Company had approximately $3,037,000 and $3,477,000 in deferred income balances related to this grant for the nine months ended September 30, 2024 and the year ended December 31, 2023, respectably.

Johnson and Johnson Quickfire Grants

The Company received a grant from the Johnson and Johnson through the U.S. government's Blue Knight Program (Quickfire Grant) for experiments relating to the pharmacokinetics and tolerability of the aforementioned *pan-Coronavirus* inhibitor in the Human Airway Epithelium (HAE) model. The initial award to the Company in January 31, 2023 provided for $100,000. The Company initially recorded the proceeds in deferred income. As work was commenced under the grant the company recognizes income from deferred income.

In September 22, 2023 the Company received the first $500,000 of an additional Quickfire grant for $1,000,000 for work to investigate the potential for broader therapeutic use of the aforementioned *pan-Coronavirus* inhibitor. The Company initially recorded the proceeds in deferred revenue. As work was commenced under the grant the company recognizes income from deferred income.

In December 1, 2023 the Company received an the second $500,000 of the Quickfire grant mentioned above. The Company initially recorded the proceeds in deferred income. As work was commenced under the grant the company recognizes income from deferred income.

The Company recognized income of approximately $763,000 and $141,000 in the nine months ended September 30, 2024 and 2023, respectively. The Company had approximately $155,000 and $458,000 in deferred income balances related to these grants for the nine months ended September 30, 2024 and the year ended December 31, 2023, respectably.

NOTE 11 – SHAREHOLDERS' EQUITY (DEFICIT)

As of September 30, 2024, the total authorized capital stock of the Company was 8,000,000 shares, which consisted of 5,000,000 shares of Common Stock, $0.001 par value per share; 1,000,000 shares of Nonvoting Common Stock $0.001 par value per share; 2,000,000 shares of Preferred Stock, $0.001 par value per share.

Common stock

At September 30, 2024 and December 31, 2023, the Company has authorized 5,000,000 shares of Common Stock, par value $0.001 per share, of which, 1,287,930 were issued.

General

The voting, dividend and liquidation rights of the holders of shares of Common Stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. The Common Stock has the following characteristics:

Voting

The holders of shares of Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders and written actions in lieu of meetings.

Dividends

The holders of shares of Common Stock are entitled to receive dividends, if and when declared by the board of directors. Cash dividends may not be declared or paid to holders of shares of Common Stock until paid on each series of outstanding preferred stock in accordance with their respective terms. As of September 30, 2024, no dividends have been declared or paid since the Company's inception.

Liquidation

After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of the Common Stock are entitled to share ratably in the Company's assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

Preferred stock

At September 30, 2024 and December 31, 2023, the Company authorized 2,000,000 shares of $0.001 per share par value preferred stock, of which none have been issued.

Nonvoting Common stock

At September 30, 2024 and December 31, 2023, the Company authorized 1,000,000 shares of $0.001 per share par value Nonvoting Common Stock, of which, none have been issued.

General

The voting, dividend and liquidation rights of the holders of shares of Nonvoting Common Stock are subject to and qualified by the rights, powers and preferences of the holders of shares of preferred stock. The Nonvoting Common Stock has the following characteristics:

Voting

The holders of shares of Nonvoting Common Stock are not entitled to vote. Only in special and limited case where mandated by Delaware law, Nonvoting shareholders shall be entitled to one half (½) vote for each share of Nonvoting Common Stock.

Dividends

The holders of shares of Nonvoting Common Stock are entitled to receive dividends on a one for one basis, if and when declared by the board of directors on Common Stock. Cash dividends may not be declared or paid to holders of shares of Nonvoting Common Stock until paid on each series of outstanding preferred stock in accordance with their respective terms. For the nine months ended September 30, 2024 and 2023, no dividends have been declared or paid since the Company's inception.

Liquidation

After payment to the holders of shares of preferred stock of their liquidation preferences, the holders of the Nonvoting Common Stock are entitled to share ratably in the Company's assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or upon the occurrence of a deemed liquidation event.

Warrants

As noted in Note 4, Senior Secured Convertible Promissory Notes, the Company issued an additional 123,171 warrant shares during the nine months ended September 30, 2024. As of September 30, 2024 these warrants have not been exercised and remain outstanding.

	Warrants	Weighted Average Exercise Price	Weighted Average Contractual Terms
Outstanding at December 31, 2023	232,092	$ 10.47	3.50
Granted	123,171	14.78	
Forfeited/Cancelled	—	—	
Outstanding at September 30, 2024	355,263	$ 11.96	3.63

As of September 30, 2024, outstanding warrants expire in with dates between June 19, 2027 and September 11, 2029, and have a fair value of $305,465.

NOTE 12 - CONTINGENCIES

From time to time, the Company may become involved in various legal matters arising in the ordinary course of business. Management is unaware of any matters requiring accrual for related losses in the financial statements.

NOTE 13 - SUBSEQUENT EVENTS

Management has evaluated subsequent events through January 8, 2025, which is the date the financial statements were available to be issued. Other than disclosed below, there were no subsequent events that require adjustment or disclosure in the consolidated financial statements.

On October 30, 2024, the Company issued convertible notes with principal amount of $250,000, with a Company option to call an additional $250,000 under equivalent terms. These notes will convert into shares of the Company's Common Stock at a price of $5.23 per share in a manner substantially similar to the conversion rights under the Senior Secured Convertible Notes described above, have an annual interest rate of 10%, and a maturity date 180 days from the date of issuance.

In December 2024, the Company issued three convertible notes with principal amount of $375,000. These notes will convert into shares of the Company's Common Stock at a price of $5.23 per share in a manner substantially similar to the conversion rights under the Senior Secured Convertible Notes described above, have an annual interest rate of 10%, and a maturity date 180 days from the date of issuance.

Shares of Common Stock

or

Pre-Funded Warrants to Purchase up to Shares of Common Stock

Representative Warrants to Purchase up to Shares of Common Stock

Up to Shares of Common Stock Issuable Upon Exercise of Pre-Funded Warrants and Representative Warrants

PRELIMINARY PROSPECTUS

Ladenburg Thalmann

The date of this prospectus is , 2025

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the expenses to be incurred in connection with the offering described in this registration statement, all of which will be paid by the registrant. All amounts are estimates except the SEC registration fee and the Financial Industry Regulatory Authority ("FINRA") filing fee.

		Amount
SEC registration fee	$	1,220.14
FINRA filing fee	$	*
Accounting fees and expenses	$	*
Legal fees and expenses	$	*
Printing and related expenses	$	*
Transfer agent fees	$	*
Miscellaneous	$	*
Total expenses	$	*

* To be filed by amendment

Item 14. Indemnification of Directors and Officers.

Section 102 of the Delaware General Corporation Law (the "DGCL") permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Salarius' Certificate of Incorporation provides that no director shall be personally liable to Salarius or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnification for such expenses which the Court of Chancery or such other court shall deem proper.

Salarius' Certificate of Incorporation provides that Salarius will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of us), by reason of the fact that he or she is or was, or has agreed to become, Salarius' director or officer, or is or was serving, or has agreed to serve, at Salarius' request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including

attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, Salarius' best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

Salarius' Certificate of Incorporation also provides that Salarius will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of Salarius to procure a judgment in Salarius' favor by reason of the fact that the Indemnitee is or was, or has agreed to become, Salarius' director or officer, or is or was serving, or has agreed to serve, at Salarius' request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, Salarius' best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to Salarius', unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by Salarius' against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If Salarius does not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

Salarius maintains a general liability insurance policy that covers certain liabilities of Salarius' directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

Insofar as the foregoing provisions permit indemnification of directors, executive officers, or persons controlling Salarius for liability arising under the Securities Act, Salarius has been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all securities sold or granted by Salarius within the last three years that were not registered under the Securities Act and the consideration, if any, received by Salarius for such securities.

Pursuant to that certain Purchase Agreement, dated December 12, 2024, by and between Salarius and C/M Capital Master Fund, LP (the "Purchaser"), on January 13, 2025 Salarius issued and sold to the Purchaser 141,000 shares of common stock, par value $0.0001 per share (the "Purchase Shares"). As consideration for the Purchaser's execution and delivery of the Purchase Agreement and simultaneously with the delivery of the Purchase Shares purchased under the Purchase Agreement, Salarius issued to the Purchaser 1,410 shares of common stock value $0.0001 per share.

On April 22, 2022, Salarius issued and sold to certain institutional and accredited investors 46,697 shares of common stock, par value $0.0001 per share (the "April 2022 Shares"), at a purchase price of $50.00 per April 2022 Share (the "April 2022 Registered Direct Offering"). Concurrently with the April 2022 Registered Direct Offering, Salarius also sold warrants exercisable for an aggregate of 35,023 shares of common stock, with an exercise price of $67.98 per share. The warrants were exercisable six months following the issuance date and will expire five and one-half years from the issuance date. The gross proceeds from the April 2022 Registered Direct Offering was approximately $2.3 million. The warrants were sold and issued without registration under the Securities Act, in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

On May 11, 2023, Salarius issued and sold to an accredited investor (i) 41,250 shares of common stock, par value $0.0001 per share (the "May 2023 Shares"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 413,296 shares of common stock, (iii) Series A-1 warrants (the "Series A-1 Warrants") to purchase up to

454,546 shares of common stock and (iv) Series A-2 warrants (the "Series A-2 Warrants" and together with the Series A-1 Warrants, the "Common Stock Warrants," and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 454,546 shares of common stock, at a purchase price of (a) $13.20 per May 2023 Share and accompanying Common Stock Warrants and (b) $13.1992 per Pre-Funded Warrant and accompanying Common Stock Warrants. The aggregate gross proceeds from the transaction were approximately $6.0 million, exclusive of placement agent fees and expenses and other offering expenses.

Each Series A-1 Warrant is exercisable for a period of five and one-half (5.5) years from the issuance date at an exercise price of $11.20 per share. Each Series A-2 Warrant was exercisable for a period of eighteen (18) months from the issuance date at an exercise price of $11.20 per share and expired as of November 11, 2024. Each Pre-Funded Warrant was sold in lieu of shares of common stock, was exercisable immediately upon issuance, had an exercise price of $0.0008 per share and have been exercised in full as of the date of this prospectus.

H.C. Wainwright & Co., LLC ("Wainwright") acted as the exclusive placement agent for the issuance and sale of the Shares and Warrants. Among other consideration, Salarius issued to Wainwright unregistered warrants to purchase up to 31,818 shares of common stock at an exercise price per share of $16.50 and a term of five and one-half (5.5) years (the "Placement Agent Warrant").

The Shares, the Warrants, the Placement Agent Warrant and the shares of common stock underlying the Warrants and the Placement Agent Warrants have not been registered under the Securities Act or the securities laws of any state, and are being offered and sold in reliance on the exemption from registration under the Securities Act, afforded by Section 4(a)(2) and/or Rule 506 promulgated thereunder.

From December 12, 2021 through the filing date of this prospectus, Salarius granted to its directors and officers options to purchase an aggregate of 25,154 shares of Salarius' common stock under its equity compensation plans at exercise prices ranging from $4.80 to $96.00 per share.

On January 3, 2023, Salarius issued 4,580 restricted shares of its common stock to its directors and officers.

Item 16. Exhibits and Financial Statement Schedules

a) Exhibits.

Exhibit No.	Description
1.1**	Form of Underwriting Agreement
2.1	Agreement and Plan of Merger, dated as of January 10, 2025, by and among the Registrant, Decoy Therapeutics Inc., Decoy Therapeutics MergerSub I, Inc. and Decoy Therapeutics MergerSub II, LLL. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 9, 2015).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on July 18, 2019 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).
3.3	Certificate of Amendment to Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on October 14, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on October 14, 2022).
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant filed with the Secretary of State of the State of Delaware on June 14, 2024 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 14, 2024).

3.5	Amended and Restated Bylaws of the Registrant, effective July 19, 2019 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).
3.6	Amendment to the Amended and Restated Bylaws of the Registrant, effective April 1, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 1, 2022).
4.1	Form of Common Stock Certificate of Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration statement on Form S-1 (File No. 333-201276), as amended, filed January 13, 2015 (the "S-1")).
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.8 to the Registrant's S-1 (File No. 333-201276), as amended, filed February 6, 2020).
4.3	Common Stock Purchase Warrant dated February 11, 2020 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 12, 2020).
4.4	Form of Inducement Warrant dated December 11, 2020 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K/A filed with the SEC on December 11, 2020).
4.5	Form of 2021 Flex Warrants (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 1, 2021).
4.6	Form of Common Stock Purchase Warrant dated April 26, 2022 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 22, 2022).
4.7	Form of Certificate of Designation of Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form8-K filed with the SEC on January 15, 2025).
4.8	Form of Placement Agent Warrants (incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2023).
4.9**	Form of Pre-Funded Warrant
4.10**	Form of Representative Warrant
4.11**	Form of Warrant Agency Agreement
5.1**	Opinion of Hogan Lovells US LLP.
10.1+	Form of Indemnification Agreement between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on July 22, 2019).
10.2+	Indemnification Agreement, dated February 20, 2024, between Salarius Pharmaceuticals, Inc. and David J. Arthur (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).
10.3^	Exclusive License Agreement, dated August 3, 2011, between the University of Utah Research Foundation and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-4 filed with the SEC on February 14, 2019 (the "S-4")).
10.4^	Cancer Research Grant Contract, dated June 1, 2016, between the Cancer Prevention and Research Institute of Texas and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.3 to the S-4).
10.5+	Amended and Restated Executive Employment Agreement, dated February 5, 2019, between David J. Arthur and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.5 to the S-4).
10.6+	Amendment to Amended and Restated Executive Employment Agreement dated September 10, 2019, among David J. Arthur, the Registrant and Salarius Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on September 16, 2019).

10.7+	Separation and Release Agreement, dated February 20, 2024, between David J. Arthur and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2023).
10.8+	Consulting Agreement, dated February 20, 2024, between Salarius Pharmaceuticals, Inc. and David J. Arthur (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2023).
10.9+	Executive Employment Agreement, dated April 24, 2020, between Mark J. Rosenblum and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 29, 2020).
10.10+	Amendment to Executive Employment Agreement, dated February 20, 2024, between Mark J. Rosenblum and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).
10.11+	Forms of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice under the Flex Pharma, Inc. 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 24, 2015).
10.12+	Notice of Stock Option Amendment, dated February 20, 2024, between David J. Arthur and Salarius Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on February 23, 2024).
10.13+	Amended and Restated Salarius Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 15, 2023).
10.14+	Salarius Pharmaceuticals, Inc., 2015 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on June 19, 2020)
10.15	At the Market Offering Agreement, dated February 5, 2021, between Salarius Pharmaceuticals, Inc. and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on February 5, 2021).
10.16	Securities Purchase Agreement, dated April 22, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 22, 2022).
10.17	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2023).
10. 18	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 16, 2023).
10.19	Securities Purchase Agreement, dated December 12, 2024, by and between Salarius Pharmaceuticals, Inc. and C/M Capital Master Fund, LP. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on December 13, 2024).
10.20	Registration Rights Agreement, dated December 12, 2024, by and between Salarius Pharmaceuticals, Inc. and C/M Capital Master Fund, LP (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 13, 2024).
10.21	Form of Salarius Support Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).
10.22	Form of Decoy Support Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).
10.23	Form of Lock-Up Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).
10.24	Warrant Cancellation Agreement, dated as of January 10, 2025, by and among the Registrant and an Investor (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed with the SEC on January 13, 2025).

21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Form S-1).
23.2*	Consent of Ernst & Young LLP
23.3*	Consent of Fruci & Associates II, PLLC
23.4**	Consent of Hogan Lovells US LLP (included in Exhibit 5.1).
24.1	Power of Attorney (see signature page).
99.1*	Consent of Barbara Hibner to be named as a director
99.2*	Consent of Frederick Pierce to be named as a director
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definitions Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
107*	Filing Fee Table

^ Portions of this exhibit have been omitted and provided separately to the SEC pursuant to a request for confidential treatment.
+ Management contract or compensatory plans or arrangements.
* Filed herewith.
** To be filed by amendment.

(b) Financial Statement Schedules

See the index to the consolidated financial statements included on page F-1 for a list of the financial statements included in this registration statement. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to our Certificate of Incorporation or Bylaws, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by the registrant is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Houston, State of Texas on January 21, 2025.

Salarius Pharmaceuticals, Inc.

By: /s/ David J. Arthur
David J. Arthur
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints David J. Arthur and Mark J. Rosenblum, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments, including post-effective amendments, to this registration statement, and any registration statement relating to the offering covered by this registration statement and filed pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys in fact and agents or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated on the dates indicated.

Signature	Title	Date
/s/ David J. Arthur David J. Arthur	President, Chief Executive Officer, and Director *(Principal Executive Officer)*	January 21, 2025
/s/ Mark J. Rosenblum Mark J. Rosenblum	Executive Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	January 21, 2025
/s/ William K. McVicar William K. McVicar	Chairman	January 21, 2025
/s/ Tess Burleson Tess Burleson	Director	January 21, 2025
/s/ Arnold Hanish Arnold Hanish	Director	January 21, 2025
/s/ Paul Lammers Paul Lammers	Director	January 21, 2025
/s/ Jonathan Lieber Jonathan Lieber	Director	January 21, 2025
/s/ Bruce J. McCreedy Bruce J. McCreedy	Director	January 21, 2025

Calculation of Filing Fee Tables

Form S-1
(Form Type)

Salarius Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1 - Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price(1)(2)(3)	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Common Stock, par value $0.0001 per share (4)	457(o)	—	—	$6,900,000	0.00015310	$1,056.39
Fees to Be Paid	Equity	Pre-Funded Warrants to purchase Common Stock (4)(5)	Other	—	—	Included Above	—	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of Pre-Funded Warrants	457(o)	—	—	Included Above	—	—
Fees to Be Paid	Equity	Representative Warrants to purchase Common Stock (5)	Other	—	—	—	—	—
Fees to Be Paid	Equity	Common Stock issuable upon exercise of Representative Warrants (6)	457(o)	—	—	$1,069,500	0.00015310	$163.75
				Total Offering Amounts		$7,969,500		$1,220.14
						Total Fees Previously Paid		—
						Total Fee Offsets		—
						Net Fee Due		$1,220.14

(1) Estimated solely for the purpose of calculating the registration fee pursuant Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416(a) under the Securities Act, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions.

(3) Includes the price of additional shares of common stock that may be issued upon exercise of the option granted to the underwriters to cover over-allotments, if any.

(4) The proposed maximum aggregate offering price of the common stock will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants issued in the offering, and the proposed maximum aggregate offering price of the pre-funded warrants to be issued in the offering

will be reduced on a dollar-for-dollar basis based on the offering price of any common stock issued in the offering. Accordingly, the proposed maximum aggregate offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $6,900,000.

(5) No fee pursuant to Rule 457(g) of the Securities Act.

(6) The registrant has agreed to issue upon the closing of this offering, warrants to the representative of the underwriters (the "Representative Warrants") entitling it to purchase up to 10% of the number of shares of common stock and pre-funded warrants sold in this offering. The exercise price of the Representative Warrants is equal to 155% of the public offering price of the securities offered hereby. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act, the proposed maximum aggregate offering price of the Representative Warrants is $1,069,500, which is equal to 155% of $690,000 (10% of $6,900,000).

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 22, 2024 (except for the effects of the reverse stock split as described in Note 1, as to which the date is January 21, 2025) in the Registration Statement (Form S-1) and the related Prospectus of Salarius Pharmaceuticals, Inc. for the registration of common stock, pre-funded warrants, and representative warrants.

/s/ Ernst & Young LLP

Houston, Texas
January 21, 2025

Exhibit 23.3

FRUCI & ASSOCIATES II
A Professional Limited Liability Company

CONSENT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement to Form S-1, of our audit report dated November 26, 2024, with respect to the consolidated balance sheets of Decoy Therapeutics, Inc. as of December 31, 2023, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023.

Our report relating to those financial statements includes an emphasis of matter paragraph regarding substantial doubt as to the Company's ability to continue as a going concern.

We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Fruci & Associates II, PLLC

Spokane, Washington
January 21, 2025

Exhibit 99.1

January 11, 2025

Salarius Pharmaceuticals, Inc.
2450 Holcombe Blvd., Suite X
Houston, TX 77021

Consent to Reference in Registration Statement

Salarius Pharmaceuticals, Inc. (the ***"Company"***) has filed the Registration Statement on Form S-1 with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the ***"Securities Act"***). In connection therewith, I hereby consent, pursuant to Rule 438 of the Securities Act, to the reference to me in the prospectus included in such registration statement as a future member of the board of directors of the Company.

Sincerely,

/s/ Barbara Hibner

Barbara Hibner

Exhibit 99.2

January 11, 2025

Salarius Pharmaceuticals, Inc.
2450 Holcombe Blvd., Suite X
Houston, TX 77021

Consent to Reference in Registration Statement

Salarius Pharmaceuticals, Inc. (the ***"Company"***) has filed the Registration Statement on Form S-1 with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the ***"Securities Act"***). In connection therewith, I hereby consent, pursuant to Rule 438 of the Securities Act, to the reference to me in the prospectus included in such registration statement as a future member of the board of directors of the Company.

Sincerely,

/s/ Frederick (Rick) Pierce II

Frederick (Rick) Pierce II